Department of Health and Human Services Office of Inspector General

Program and Management Improvement Recommendations

The Orange Book



June Gibbs Brown Inspector General

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services' (HHS) programs as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components.

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities, and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspection reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil money penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations, and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

Introduction

What is the Orange Book

The Orange Book is a compendium of significant Inspector nonmonetary Office of improving departmental recommendations for operations. The Office of Inspector General (OIG) implementation believes that recommendations will benefit the Department and its customers through increased operational effectiveness and assurance that governmental resources are controlled by reliable financial management and accounting Generally, systems. implemented recommendations can be by administrative action, although a few call for a legislation. Although recommendations generally will have a nonmonetary impact when implemented, the Department may achieve some programmatic savings.

The Orange Book supplements other OIG reports. The Inspector General Act requires that OIGs' semiannual reports to the Congress include "...an identification of each significant recommendation described in previous semiannual reports on which corrective action has not been completed." compliance with Act, the recommendations are highlighted in the semiannual reports. Because of the abbreviated nature of these reports and the potentially significant impact of OIG recommendations, we prepare the Orange Book to elaborate further on our most significant nonmonetary issues.

Through the Orange Book, Department of Health and Human Services (HHS), Office of Management and Budget (OMB) officials, and the Congress have in one document significant program and management improvement recommendations. Recommendations for proposed legislation are not removed from the Orange Book until the law has been enacted—not just proposed. For administrative issues, recommendations are not removed until the action has been substantially completed.

The HHS Organization

The HHS is the Federal Government's principal agency for promoting the health and welfare of Americans and providing essential human services to persons of every age group.

It touches every aspect of life for each American citizen. Eighty-four (84) percent of the HHS budget provides income support and medical care coverage for the elderly, disabled, and the poor. The balance of the budget provides research into the causes of disease, promotes preventive health measures, supports the provision of health and social services, and combats alcoholism and drug abuse.

The Department operates within four program areas: Health Care Financing, Public Health, Children and Families, and Older Americans, as well as general departmental management. The OIG's findings and recommendations relating to these program areas and general management are highlighted in separate sections of this Orange Book.

- ! The Health Care Financing program area encompasses the Medicare and Medicaid programs.
- ! The Public Health service program area covers biomedical research; disease cure and prevention; the safety and efficacy of foods, drugs, and medical devices; impact of toxic waste sites on health; and other activities designed to ensure the general health and safety of American citizens.
- į The Children and Families program provides Federal direction and funding State-administered programs designed promote stability, economic security, responsibility, and self-support for the Nation's families, including a variety of social service programs for American children and families, Native Americans, and the developmentally disabled.
- ! The Older Americans program area aims at improving older Americans' quality of life through nutrition and service programs which help senior citizens remain independent for as long as possible.

Table of Contents

Health Care Financing

Ambulance	
Develop Prepayment Edit to Verify Medical Necessity of Ambulance Claims NEW	. 3
Contractor Operations	
Strengthen HCFA Regional Office Oversight of Medicare Contractors NEW Mandate Information Sharing Among Peer Review Organizations and State Medical Boards Improve Monitoring of Medicare Contractor Performance Assess Beneficiary Complaint Process of Medicare Peer Review Organizations Improve the Medicare PROs' Role in Identifying and Responding to Poor Performances Improve Evaluation of Fraud Unit Performance	. 5 . 6 . 7 . 8
HCFA Administration	
Establish a National Medicaid Credit Balance Reporting Mechanism Implement Medicaid Expansions for Prenatal Care	11
Home Health	
Improve Physician's Role in Home Health Care	13
Hospices	
Strengthen Education of Contractual Relationships Between Hospices and Nursing Homes NEW	14
Hospitals	
Review HCFA's Investigation and Resolution of Patient Dumping Complaints	16
Information and Accounting Systems	-,
Improve HCFA's Implementation of Federal Managers' Financial Integrity Act	19
Fairly Presented NEW	20
Address Administrative Deficiencies Identified by Medicare Beneficiaries	
Educate Medicare Beneficiaries About Managed Care Options	23

Improve Beneficiary Understanding of Home Health Services 2 Review the Impact of OBRA 1990 on State Regulation of Medigap Insurance 2	
Managed Care	
Consider Recommended Safeguards Over Medicaid Managed Care Programs Retooling Medicaid Agencies for Managed Care NEW Use Beneficiary Surveys As A Protection Tool for Medicaid Managed Care NEW Coordinate Medicaid Managed Care Plans with HIV/AIDS Services NEW 2	27 28
Medical Equipment and Supplies	
Improve Relationship Between Physician and Beneficiary When Ordering Medicare Equipment and Supplies NEW 3 Prevent Inappropriate Medicaid Payments for Incontinence Supplies 3	
Nursing Homes	
Ensure Appropriate Mental Health Services Delivered in Nursing Homes Improve Nursing Home Surveyor Staffing and Training NEW Develop Nurse Staffing Standards for Nursing Homes NEW Improve Dissemination of Nursing Home and Medigap Guides Improve Medicaid Estate Recovery Programs (Continued) Assess Vulnerabilities in Medicaid Asset Verification 3 3 3 3 3 4 3 3 3 4 3 3 4 3 4 5 5 6 7 7 8 7 8 7 8 7 8 7 8 7 8 8	33 34 35 36 37
Physicians/Allied Health Professionals	
Ensure Equal Distribution of Organs for Transplantation	1 2 4 5 6 8
Prescription Drugs	
Provide Additional Guidance to Drug Manufacturers to Better Implement the Medicaid Drug Rebate Program	

Public Health

Biomedical Research	
Comply with Federal Printing Program Requirements NEW	5 6
Food and Drug Safety	
Improve the Process by Which Blood Establishments Notify FDA of Errors and Accidents Affecting Blood	9 0 1
Health Resources and Services	
Require Participation in the 340B Drug Pricing Program for All Eligible Entities NEW	3
Indian Health	
Improve Management of the Office of Program Integrity and Ethics NEW	4
PHS Administration	
Strengthen Policies and Procedures for Medical Personnel Credentialing and Privileging at IHS and HRSA NEW 6 Establish an FDA Performance Measurement System in Compliance with the Prompt Payment Act NEW 6 Develop Plan to Address Youth Use of Cigars NEW 6 Expand Dissemination of Treatment Improvement Protocols NEW 6	6
Substance Abuse and Mental Health	
Develop Performance Measures for Detoxification Services for Medicaid Beneficiaries NEW 6	9

Children and Families

100	4	7	•	•		. •	
ACF	\boldsymbol{A}	an	11 <i>I</i>	LLS	tr	atıc	m

Consider Options for Assisting States in Effectively Managing the Federal Foster Care Program	72
Child Support Enforcement Collection Process	
Review Availability of Health Insurance for Title IV-D Children NEW	73 74
Children, Youth, and Family Services	
Develop Effective Practices for Handling Facility Purchases by Head Start Program Grantees . Improve Implementation of Interstate Compact for Placement of Children NEW Provide Guidance to Correct Vulnerabilities and Barriers to State's Child Care Certificate	76
Systems NEW	77
Grants Management	
Improve Oversight of Single Audits of Office of Community Services Grants	79

Older Americans

4 4	4 1		• .	. •
AoA	Ad	min	istra	ation

	Strengthen the Long Term Care Ombudsman Program NEW	82
Nu	trition and Services	
	Improve Nutrition for the Elderly by Using U.S. Department of Agriculture Commodities	83
	Collocate Intergenerational Programs	84
	Improve Safeguards for Long-Term-Care Residents NEW	85

General Department Management

Financial Management

Update Cost Principles for Federally Sponsored Research Activities	88
Incorporate Provisions for Implementing FASB 106 in Guidelines to Reimburse	
Educational Institutions and Nonprofit Organizations	89
Improve Recharge Centers' Financial Accounting Systems	90
Improve Financial Reporting Processes NEW	91
(Continued) NEW	92
Improve Accounting for Property, Plant, and Equipment at NIH and FDA NEW	93

Overview

The Medicare program provides health care coverage for an estimated 37 million individuals. Medicare Part A (hospital insurance) provides, through direct payments for specified use, hospital

insurance protection for covered services to persons age 65 or older and to certain disabled persons. Medicare Part B (supplementary medical insurance) provides, through direct payments for specified use, insurance protection against most of the costs of health care to persons age 65 and older and certain disabled persons who elect this coverage. The services covered are medically necessary physician services, outpatient hospital services, outpatient physical therapy, speech pathology services, and certain other medical and health services.

The Medicaid program provides grants to States for medical care for more than 35 million low-income people. Federal matching rates were determined on the basis of a formula that measures relative per capita income in each



Introduction

State. Eligibility for the Medicaid program is, in general, based on a person's eligibility for cash assistance programs. The newly created Federal/State Children's Health Insurance Program (CHIP) expands health coverage to uninsured children whose families earn too much to qualify for Medicaid but too little to afford private coverage.

Highlights of OIG Activities

The Office of Inspector General (OIG) activities that pertain to the health insurance programs administered by the Health Care Financing Administration help ensure cost-effective health care, improve quality of care, address access to care issues, and reduce the potential for fraud, waste, and abuse. Through audits, evaluations, and inspections, OIG recommends changes in legislation, regulations, and systems to improve health care delivery systems and reduce unnecessary expenses. The OIG's reviews assess the adequacy of internal controls, identify innovative cost containment techniques, probe for improper cost shifting, seek to identify mechanisms to contain increasing Medicare/Medicaid costs, and identify efficiencies in program administration.

Orange Book 1998-99 Page 2 of 93

Develop Prepayment Edit to Verify Medical Necessity of Ambulance Claims

Report Number: OEI-09-95-00412 Final Report: 11/98

Finding

We found that two-thirds of ambulance services that did not result in hospital or nursing home admissions or emergency room care on the same date of services were medically unnecessary. We estimate that Medicare allows approximately \$104 million each year for these medically unnecessary ambulance services.

Current Law/Policy

The HCFA regulations state that ambulance services are covered only if other forms of transportation would endanger the beneficiary's health. The Balanced Budget Act of 1997 (BBA) mandates that HCFA work with the industry to establish a negotiated fee schedule for ambulance payments effective January 1, 2000.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

The HCFA should develop a prepayment edit to verify the medical necessity of ambulance claims that are not associated with hospital or nursing home admissions or emergency room care. This proposal would provide a solution for one group of ambulance services until HCFA and the industry can better address issues of medical necessity, including clear and consistent definitions.

Status

Management Response

In comments on our draft report, HCFA concurred with the need for medical review of these types of ambulance claims. However, because of resource demands associated with Y2K, HCFA does not believe it can implement such an edit prior to the major overhaul of ambulance payment policies required by the BBA. Instead, HCFA intends to ask its carriers to review their ambulance data and decide whether edits accompanied by local medical review policies or focused medical review of potential aberrant providers are appropriate. In addition, HCFA has assigned an independent contractor to perform analysis related to non-emergency ambulance transportation.

Orange Book 1998-99 Ambulance Page 3 of 93

Strengthen HCFA Regional Office Oversight of Medicare Contractors

Report Number: OAS-17-97-00097 Final Report: 4/98

OAS-17-98-00098 2/99

Finding

Our audit of HCFA's FY 1998 financial statements identified continuing problems with the internal control procedures used by HCFA's regional offices to evaluate Medicare contractors' compliance with contracts, laws, and regulations. Medicare contractors prepare and submit periodic financial reports to HCFA for use in preparing HCFA's financial statements. However, oversight activities were not adequate to ensure that financial data provided by the contractors were reliable, accurate, and complete.

Current Law/Policy

The HCFA regional offices have oversight responsibility for Medicare contractors. Guidance for the oversight effort is found in the Contractors Performance Evaluation review process.

Recommendation	Legislative	✓ Administrative	Material Weakness
	<u> </u>	V Transmistrative	TVIACCITAT VV CARTICUS

We recommended that HCFA (1) increase its oversight of Medicare contractors' financial reporting data, (2) issue instructions that specify the expectations and the procedures to be performed by regional offices to ensure that HCFA 750/751 and HCFA 1522 reports are submitted timely and are properly reconciled to accounting records, (3) periodically test the validity of submitted financial information and obtain supporting documents, (4) increase the contractor population which will encompass a greater number of providers, and (5) develop corrective action plans for resolving past as well as current OIG financial statement findings and recommendations and follow up to determine effective implementation.

Status

Management Response

The HCFA has developed a corrective action plan and has improved many of the Medicare oversight procedures performed by the regional offices. However, certain procedures were not adequate or were not performed consistently in all regions to ensure that financial data provided by contractors were reliable, accurate, and complete.

Orange Book 1998-99 Contractor Operations Page 4 of 93

Mandate Information Sharing Among Peer Review Organizations and State Medical Boards

Report Number: OEI-01-92-00530 Final Report: 4/93

Finding

Because of the uncertainty of the meaning of "notice and hearing" in the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), peer review organizations (PROs) still share little information with medical boards. For example, in a November 1992 report the Citizens Advisory Center, which is funded by the American Association of Retired Persons, documented that with the exception of a few States, very little information sharing is taking place.

Current Law/Policy

Congress, in Section 4205 (d) of OBRA 90, required that PROs notify State medical boards of physicians found responsible for serious quality of care problems. Congress stipulated, however, that notification is not to occur until after "notice and hearing" are granted to the physicians involved.

Recommendation v	Legislative	Administrative	Material Weakness
------------------	-------------	----------------	-------------------

The HCFA should propose legislation mandating that PROs provide case information to State medical boards when they have confirmed, after medical review, that a physician is responsible for medical mismanagement of care resulting in significant adverse effects to the patient.

Status

Management Response

The HCFA disagreed with our recommendation. The HCFA believes the recommendation for legislation would not solve the problem because of confusion created by the "notice and hearing provision" of the current legislation. The HCFA developed a model Memorandum of Agreement (MOA) in 1994 for PRO's and State licensing and certification agencies to utilize in order to facilitate ongoing, routine exchange of agreed upon information.

Orange Book 1998-99 Contractor Operations Page 5 of 93

8/95

Improve Monitoring of Medicare Contractor Performance

Finding

Final Report:

The HCFA has not yet made full use of the information gathered under its new review approach to further contractors' ability to safeguard Medicare payments.

Current Law/Policy

Report Number: OEI-01-93-00160

In the past, HCFA has used the Contractor Performance Evaluation Program (CPEP) to monitor contractor performance. The CPEP used a numerical scoring system on a wide range of performance criteria. One feature of the new approach is a qualitative assessment of contractors' strengths and weaknesses. Rather than a numeric score, this new process produces a written narrative.

Recommendation	I agiclativa	Administrative	Material Weakness
Recommendation	Legislative	A dministrative	Material Weaknes

The HCFA central office should: (1) ensure that they receive information from the regional offices about how they are monitoring contractor improvement plans that resulted from these reviews, (2) provide guidance for review teams regarding key information to be contained in the written reports, (3) prepare an analysis of effective practices and practices to avoid based on findings from the 1994 review process, and (4) share these analyses with all fiscal intermediaries and carriers.

Status

Management Response

The HCFA concurs with the recommendations and is working with the regional offices to develop mechanisms for monitoring the performance improvement plans. In order to enhance ongoing contractor oversight and provide consistency in the review process, HCFA implemented a new National Contractor Performance Evaluation Strategy in May 1999. This new effort is a nationwide multi-tired approach and focuses review on key, high risk contractors and program benefits categories. This strategy addressed specific recommendations in the OIG report.

Orange Book 1998-99 Contractor Operations Page 6 of 93

Assess Beneficiary Complaint Process of Medicare Peer Review Organizations

Report Number:	OEI-01-93-00250	Final Report:	10/95	
Finding				
	organization (PRO) proking the beneficiary con		n several problems which ffective.	create
Current La	w/Policy			
	ndget Reconciliation Adverselated complaints re	,	c Law 99-509) requires PR dicare beneficiaries.	ROs to review
Recommer	dation	Legislative	A dministrative	Material Weakness
complaint procesto the complaint.	ss. Toward that end, He This is the standard to	CFA should: (1) which the Joint	ctive ways to correct the floor Require PROs to respond Commission on the Accre The HCFA should give the	d substantively ditation of

Status

Management Response

The HCFA concurs with our recommendation to identify cost-effective ways to enhance Medicare beneficiaries' awareness of PROs and to correct the flaws in the complaint process. The HCFA participates on the Beneficiary Protection and Documentation Issues Task Force of the Medicare Technical Advisory Group. The HCFA has an online brochure explaining the beneficiary complaint process and listing 1-800 numbers of all PROs. The HCFA plans to put information on the beneficiary complaint process on the Internet. Also, regulations are under development to enable PROs to provide more substantive responses to complaints. Finally, in July 1998, HCFA awarded a special study to 8 PROs to evaluate alternative methods to the beneficiary complaints process currently in use. The study will be completed by the end of July 1999 and a final report is due to HCFA on August 31, 1999. The HCFA will put information on the beneficiary complaint process on the Internet by December 1999.

priority. (2) Identify cost-effective ways to enhance Medicare beneficiaries' awareness of PROs

and the complaint process. (3) Streamline the complaint process.

Orange Book 1998-99 Contractor Operations Page 7 of 93

Improve the Medicare PROs' Role in Identifying and Responding to Poor Performances

Final Report: 12/95

Finding
The peer review organizations (PRO) are having difficulty pursuing both the goal of continuous improvement and action on poor performing providers.
Current Law/Policy
Under the Fourth Scope of Work, PROs' focus has been changed from case review to continuous quality improvement. The PROs still have responsibility for initiating projects and taking action to identify and deal with poor performing providers.
Recommendation Legislative Administrative Material Weakness
The HCFA should consider options for strengthening PROs' roles in identifying and taking action on poor performers or assigning this role to other entities in the quality assurance network.
Status

Management Response

Report Number: OEI-01-93-00251

The HCFA does not consider strengthening PROs' roles in identifying and taking action to deal with poor performing providers to be cost effective.

Orange Book 1998-99 Contractor Operations Page 8 of 93

Improve Evaluation of Fraud Unit Performance

Report Number: OEI-03-97-00350 Final Report: 11/98

Finding

Fiscal intermediary fraud units differed substantially in the number of complaints and cases handled. Some units produced few, if any, significant results. Despite HCFA's expectation that fraud units proactively identify fraud, half of the fraud units did not open any cases proactively. More than one-third of fraud units did not identify program vulnerabilities.

Current Law/Policy

Fiscal intermediaries are companies under contract with HCFA to administer a major part of the Medicare program. As of 1993, HCFA requires that fiscal intermediaries and carriers have distinct units to detect and deter fraud and abuse. From 1993 through 1997, funding was based mainly on the contractors' claim volume. However, in Fiscal Year 1998, HCFA changed the funding methodology to take into account the contractors' workload, risk, and performance. All fraud units must meet requirements outlined in the Medicare Intermediary Manual: identify program vulnerabilities; proactively identify fraud within their service area and take appropriate action; determine factual basis of complaints of fraud made by beneficiaries, providers, HCFA, Office of Inspector General and other sources; and initiate action to deny or suspend payments where there is reliable evidence of fraud.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

The HCFA should: (1) Improve the contractor performance evaluation system so that it not only encourages continuous improvement, but also holds contractors accountable for meeting specific objectives. (2) Require that all contractor performance evaluations list HCFA's national and regional objectives and address whether or not the fraud unit is meeting those objectives. (3) Establish a standard set of data that can be used to measure fraud units' performance in meeting established objectives and require that all contractor performance evaluation reports contain this data. (4) Establish clear definitions of key words and terms, disseminate these definitions and require that program integrity staff and fraud unit staff use the same definitions. In a future update of the Medicare Intermediary Manual, HCFA should revise sections so that these word are consistently used to mean the same thing. (5) Provide opportunities for fraud units to exchange ideas, compare methods, and highlight best practices relating to fraud and abuse detection.

Status

Management Response

The HCFA concurred with our recommendations. The HCFA stated that they (1) implemented specific national objectives, (2) designed a new program integrity management information system and are currently soliciting comments from the regional offices, (3 & 4) have consortium-wide members on the Fraud Unit Task Force who will be considering further enhancements to recently developed contractor performance evaluation criteria for FY 2000 and any additional data metrics to encourage and measure contractor performance, (5) held Benefit Integrity Training at four locations during May and June 1999 that has educated regional office and contractor benefit integrity staff on methods and expectations for improved fraud unit performance.

Establish a National Medicaid Credit Balance Reporting Mechanism

Report Number: OAS-05-93-00107 Final Report: 5/95 OAS-04-92-01023 3/93

Finding

Previous OIG reports indicated that significant amounts of outstanding Medicaid credit balances exist nationwide. Currently, many State agencies' efforts are inadequate to ensure that, nationwide, the majority of Medicaid credit balances are being identified by providers and overpayments recovered in a timely manner.

Current Law/Policy

The HCFA does not require State agencies to routinely monitor providers' efforts to identify and refund Medicaid credit balances in patient accounts.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

The HCFA should establish a national Medicaid credit balance reporting mechanism similar to the Medicare Part A credit balance reporting procedures. Also, HCFA should require its regional offices to actively monitor the reporting mechanism established.

Status

Management Response

The HCFA agreed to recover estimated outstanding credit balances and to perform an evaluation of State agencies' oversight activities. Initially, HCFA also agreed with the recommendation to establish a national Medicaid credit balance reporting mechanism similar to HCFA's Medicare Part A credit balance reporting mechanism. Upon reexamination, HCFA decided not to do so, citing the uncertain but minimal savings potential and the Administration's commitment to enhancing States' flexibility and, specifically, to avoiding the imposition of unfunded mandates.

Orange Book 1998-99 HCFA Administration Page 10 of 93

2/92

Implement Medicaid Expansions for Prenatal Care

Final Report:

Significant problems prevent newly eligible women from receiving Medicaid-covered prenatal care: (1) client outreach is inadequate and (2) women are not completing the cumbersome application process.

Current Law/Policy

States are mandated to set income eligibility at 133 percent of the Federal Poverty Level; guarantee continuous eligibility until 60 days post partum; extend the presumptive eligibility period up to 60 days for States choosing this option; use special pregnancy-related application forms; use application sites other than where Aid to Families with Dependent Children applications are processed; and eliminate paternity establishment as a precondition to receive Medicaid-covered prenatal care.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

The HCFA should: (1) develop a comprehensive outreach strategy, and (2) simplify and streamline the application process.

Status

Management Response

Report Number: OEI-06-90-00160

The HCFA concurred and agreed to continue to work with PHS, ACF, and the State Medicaid Directors.

Due to the new Welfare Reform and States opting to enroll Medicaid recipients into managed care programs, outreach strategies have increased. Many States have developed strategies targeted to provide continuous eligibility to pregnant women. States are also simplifying and streamlining application forms to alleviate administrative burdens and expedite the process.

Orange Book 1998-99 HCFA Administration Page 11 of 93

(Continued 2)

Report Number: OEI-06-90-00160 Final Report: 2/92

Finding

In evaluating Medicaid expansions for prenatal care, the OIG found that: (1) States have difficulty recruiting prenatal care providers. There is a shortage of obstetricians to deliver adequate care. (2) States need more timely information and training from HCFA. (3) The HCFA and most States cannot measure the progress and impact of expansions due to lack of centralized data.

Current Law/Policy

States are mandated to set income eligibility at 133 percent of the Federal Poverty Level; guarantee continuous eligibility until 60 days post partum; extend the presumptive eligibility period up to 60 days for States choosing this option; use special pregnancy-related application forms; use application sites other than where Aid to Families with Dependent Children applications are processed; and eliminate paternity establishment as a precondition to receive Medicaid-covered prenatal care. Congressional concern about the health status of pregnant women has led to significant Federal and State Medicaid eligibility expansions.

Recommendation Legislative Administrative Material Weaknes

The HCFA should: (1) develop incentives to increase provider participation; (2) clarify policy and monitor implementation of Medicaid expansions for prenatal care; and (3) develop data collection systems and evaluation processes to measure progress of the eligibility expansions and future program effects.

Status

Management Response

The Balanced Budget Act of 1997 repealed Section 1926 of prior law, which contained requirements that States assure adequate Medicaid payment levels for obstetrical and pediatric services.

The HCFA works closely with State Medicaid Directors, informs States of legislative options and mandates and conducts local site visits on an ongoing basis. The Medicaid Maternal and Child Health Technical Assistance Group discusses areas where technical assistance is needed and plans for action to resolve those difficulties on a regular basis.

Orange Book 1998-99 HCFA Administration Page 12 of 93

Improve Physician's Role in Home Health Care

Report Number: OEI-02-94-00170 Final Report: 6/95

Finding

Agencies and physicians identify some obstacles and issues related to the physician role. Obstacles mentioned by respondents include: (1) sixty-five percent of agencies and 51 percent of physician respondents find the process of reviewing and signing plans of care burdensome; (2) physicians find it difficult to find important information on the plan of care; and (3) some agencies feel physician awareness and education in home health is inadequate and that they lack an understanding of the home health benefit.

Current Law/Policy

Medicare home health agency regulations require physicians to sign a plan of care specifying all services the patient is to receive. This certification must be updated every 60 days, but the doctor is not required to see the patient.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

The HCFA should continue its efforts to change the plan of care to ensure it conveys critical information to caregivers and relieves unnecessary burden from physicians. The HCFA should strengthen its efforts to educate both agencies and physicians about its policies regarding the physician's role in home health care.

Status

Management Response

The HCFA has proposed revised conditions of participation for care planning and coordination of services. Specifically, the revisions would decrease the burden of home health agencies and would allow agency staff to develop care plans in coordination with the physician. The NPRM was published on March 10, 1997.

The HCFA also plans to issue new billing instructions for carriers to install new edits and conduct provider education.

Orange Book 1998-99 Home Health Page 13 of 93

Strengthen Education of Contractual Relationships Between Hospices and Nursing Homes

Report Number: OEI-05-95-00251 Final Report: 11/97

Finding

We found that some hospice contracts with nursing homes contain provisions that raise questions about inappropriate patient referrals between hospices and nursing homes.

Current Law/Policy

Hospice care is a treatment approach which recognizes that the impeding death of an individual warrants a change focus from a curative to palliative care. The Medicare hospice benefit program began in 1983 and was expended in 1986 to cover individuals residing in nursing facilities. To qualify, a patient must be certified as terminally ill with a life expectancy of 6 months or less if the illness runs its normal course.

Recommendation	Legislative	A dministrative	Material Weaknes
----------------	-------------	------------------------	------------------

We recommend that HCFA work with the hospice associations to educate the hospice and nursing home communities to help them avoid potentially fraudulent and abusive activities that might influence decisions on patient benefit choices and care.

Status

Management Response

The HCFA concurred with our recommendation. The HCFA staff, their contractors, and the regional home health intermediaries (RHHIs), are working together with the national and local hospice associations to educate them regarding potentially fraudulent and abusive activities. The RHHIs have been instructed to conduct educational seminars for providers, physicians, and/or consumers. The HCFA will also continue to encourage the RHHIs to re-emphasize the potential fraudulent and abusive activities in their continuing educational efforts.

Review HCFA's Investigation and Resolution of Patient Dumping Complaints

		Complaint	
Report Number:	OAS-06-93-00087	Final Report:	4/95

Finding

We assessed HCFA's effectiveness in investigating and resolving complaints involving potential violations of the Examination and Treatment for Emergency Medical Conditions and Women in Labor Act. We found that HCFA regional offices were not always consistent in (1) conducting timely investigations of patient dumping complaints, (2) sending acknowledgements to complainants, (3) ensuring that provisions of the Act were addressed in substantiating violations, or (4) ensuring that violations were referred to the OIG for consideration of civil monetary penalties.

Current Law/Policy

Section 1867 of the Social Security Act, "Examination and Treatment for Emergency Medical Conditions and Women in Labor," prohibits patient dumping.

We recommended that HCFA amend its guidelines to the regional offices, conduct training on the requirements concerning patient dumping, ensure that all regional offices follow established procedures, and improve its process for referring cases to the OIG.

Status

Management Response

The HCFA concurred with our findings and recommendations.

Properly Account for Medicare Secondary Payer Overpayments

Report Number: OAS-09-89-00100 Final Report: 3/90

OEI-07-90-00763 11/91

Finding

Although agreement was reached to relieve all Blue Cross and Blue Shield plans of past due Medicare Secondary Payer (MSP) overpayments and there is a 3-year future plan to identify MSP situations, it applies only to the Blue Cross and Blue Shield plans and not to all other insurance companies. Additional measures continue to be needed to help in the collection of accurate and timely information on other primary payers. This will help to reduce future Medicare overpayments which result from unidentified MSP cases and help the recovery process for overpayments.

Current Law/Policy

Medicare is the secondary payer to certain employer group health plans in instances where medical services were rendered to Medicare-enrolled employees or to their Medicare-enrolled spouses. Medicare is also the secondary payer in situations involving coverage under Worker's Compensation; black lung benefits; automobile, no fault or liability insurance; Veterans Administration programs; and end-stage renal disease and disabled beneficiary provisions. The HCFA provides administrative funds to Medicare contractors to monitor and collect MSP claims paid on behalf of Medicare beneficiaries.

Although agreement was reached to relieve Blue Cross and Blue Shield plans of past-due MSP overpayments, HCFA should continue to implement financial management systems to ensure all overpayments (receivables) are accurately recorded.

Status

Management Response

In our effort to improve financial management systems, HCFA is currently developing requirements for the Recovery Management and Accounting System. The system is intended to track all MSP activities from discovery through final disposition.

Perform Routine Monitoring of Hospital Billing Data to Identify Aberrant Patterns of Upcoding

Report Number: OEI-01-98-00420 Final Report: 1/99
OEI-03-98-00370 3/99
OEI-03-98-00490 4/99
OEI-03-98-00560 12/98

Finding

The diagnosis related group (DRG) system is vulnerable to abuse by providers who wish to increase reimbursement inappropriately through upcoding, particularly within certain DRGs. We identified a small number of hospitals that have atypically high billings for DRGs 416, 296, and 475, but found that HCFA performs no such routine, ongoing analysis of hospital billing data to detect possible problems in DRG coding.

Current Law/Policy

Under Medicare's prospective payment system reimbursement formula, the payment a hospital receives is based upon an individual hospital's payment rate and the weight of the DRG to which a case is assigned. Since 1995, HCFA has used two specialized contractors called Clinical Data Abstraction Centers to validate the DRGs on an annual national sample of over 20,000 claims billed to Medicare. This validation provides HCFA with an overall assessment of DRG coding.

Recommendation Legislative Administrative Material Wea
--

The HCFA should perform routine monitoring and analysis of hospital billing data and clinical data to proactively identify aberrant patterns of upcoding. This analysis should include identification of hospitals with atypically high billings for DRGs.

Status

Management Response

The HCFA concurred with our recommendation. The HCFA stated that under the peer review organization (PRO) contracts that will take effect between August 1999 and February 2000, PROs will conduct a Payment Error Prevention Program for inpatient hospital care. Under this approach, HCFA will conduct an independent ongoing surveillance of inpatient payment error rates, both nationally and on a State-by-State basis. The HCFA will also conduct analyses of discharge patterns and provide the results to the PROs. The PROs will conduct additional analyses of discharge patterns and take steps to reduce or eliminate erroneous billing.

Orange Book 1998-99 Hospitals Page 17 of 93

Improve HCFA's Implementation of Federal Managers' Financial Integrity Act

Report Number: OAS-14-93-03026 Final Report: 6/94

OAS-14-92-03009 10/93 OAS-14-91-03413 7/92

Finding

Although HCFA had expanded its inventory of financial management systems, we continue to believe that the Common Working File (CWF) should be subject to Federal Managers' Financial Integrity Act (FMFIA) requirements.

Current Law/Policy

The FMFIA requires each executive agency, on the basis of an evaluation conducted in accordance with guidelines prescribed by OMB, to prepare a statement each year that certifies whether or not the agency's systems of internal accounting and administrative control and financial management systems comply with the requirements of the FMFIA and OMB circulars.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

We recommended that HCFA reevaluate its review of CWF to ensure that all functional responsibilities of the system are included in FMFIA reviews.

Status

Management Response

The HCFA still does not agree that it needs to expand financial management reviews to other systems, such as CWF.

Ensure That the Medicare Accounts Receivable Balance Is Fairly Presented

Report Number: OAS-17-95-00096 Final Report: 7/97

OAS-17-97-00097 4/98 OAS-17-98-00098 2/99

Finding

Our audit of HCFA's FY 1998 financial statements, which followed up on our FY 1996 and 1997 audits, identified continuing problems with the internal control procedures used by HCFA and its Medicare contractors in processing Medicare accounts receivable transactions. These internal controls were still not adequate to reduce to a low level the risk that the accounts receivable balance could be materially misstated. Because of insufficient documentation, we were again not able to satisfy ourselves as to the fair presentation of the Medicare accounts receivable balance (\$3.6 billion in FY 1998).

Current Law/Policy

Guidance applicable to Medicare is in the Government Management Reform Act of 1994 and OMB Bulletin 98-08.

Recommendation	Legislative	✓ Administrative	\checkmark	Material Weakness
----------------	-------------	-------------------------	--------------	-------------------

We recommended that HCFA (1) review and monitor the accounts receivable internal control structure to provide reasonable assurance that reported amounts are valid and documented; (2) establish an integrated financial management system to promote consistency and reliability in recording and reporting accounts receivable information; (3) ensure that all contractors establish a general ledger system that incorporates double-entry bookkeeping; (4) enhance contractor cash controls by emphasizing the importance of segregation of duties, reconciliation processes, and other cash control techniques; (5) develop control procedures to provide independent checks by management of the validity, accuracy, and completeness of the amounts reported to HCFA; (6) ensure that contractors receive ongoing training on HCFA 750/751 reports; (7) develop appropriate input/output controls for routinely reviewing the HCFA 750/751 reports; (8) revise reporting requirements to reflect HCFA's need to retain proper documentation to support the reported balances; and (9) explore obtaining software to reduce the manual manipulation of data necessary to develop financial statements.

Status

Management Response

The HCFA has contracted with a consulting service to assist in validating the accuracy and completeness of approximately \$23 billion in accounts receivable activity reported by HCFA's Medicare contractors during FY 1998. Additional contract objectives are to reconfirm the FY 1998 ending balance and the activity for the first 6 months of FY 1999 and to recommend any accounting procedural changes or adjustments needed to fairly present these amounts.

Ensure That the Medicaid Accounts Receivable and Accounts Payable Balances Are Fairly Presented

Report Number: OAS-17-95-00096 Final Report: 7/97 OAS-17-97-00097 4/98

OAS-17-98-00098 2/99

Finding

In prior years, the State survey information that HCFA received on Medicaid accounts receivable was limited and difficult to use in accurately estimating the total Federal share of accounts payable and accounts receivable. The HCFA worked with the States to increase the response rate and the quality of information provided in FY 1998. However, auditors still must make analytical reviews of these estimates to determine their reasonableness.

Current Law/Policy

Guidance applicable to Medicaid is in the Government Management Reform Act of 1994 and OMB Bulletin 98-08.

Recommendation Legislative Administrative Material Weakness

The HCFA should continue its annual survey process or find a suitable alternative to estimate the net accounts payable amount. Trend data on accounts receivable and accounts payable over time should be developed for each State and used to improve and further refine the estimation model.

Status

Management Response

The HCFA sent the FY 1998 survey to the States well in advance of the due date.

Improve Medicare EDP System Controls

Report Number: OAS-17-98-00098 Final Report: 2/99

Finding

Controls associated with the general data processing environment (general controls) are critical to ensuring the reliability, confidentiality, and availability of data. However, numerous EDP control weaknesses were found at selected Medicare contractors. Specifically, we found deficiencies in entity-wide security programs, access controls, application development and program change controls, segregation of duties, systems software, and service continuity. Additionally, the prior year material control issue and the majority of the reportable conditions at HCFA's central office are outstanding. Overall, access controls, as well as shared systems application controls, are being reported as material weaknesses.

Current Law/Policy

The Federal Financial Management Improvement Act of 1996 requires Federal agencies to maintain acceptable accounting systems. Also, the Federal Managers' Financial Integrity Act of 1982 requires agencies to develop, maintain, and test their internal controls and financial management systems and to report any material weaknesses and planned corrective actions.

Recommendation Legislative Administrative Material Weakness

We recommended that (1) system access be properly controlled; (2) application development and program change control procedures be in place to protect against unauthorized changes; (3) computer-related duties be properly segregated; (4) service continuity plans be kept current and periodically tested; (5) a core set of Fiscal Intermediary Standard System and Common Working File (CWF) programs be defined and protected against local modification; and (6) claims be processed and approved by CWF prior to payment.

Status

Management Response

The HCFA generally concurred with the recommendations and is developing a corrective action plan.

Address Administrative Deficiencies Identified by Medicare Danafiaiariaa

		Beneficiario	es
Report Number:	OEI-04-93-00140	Final Report:	6/95

Finding

Overall, beneficiaries reported positive exerience with several key aspects of the Medicare program. Our survey identified some trouble spots such as, (1) beneficiaries having a difficult time contacting carriers by telephone; (2) beneficiaries not understanding which home health services and hospital charges Medicare paid; (3) beneficiaries unaware of Medicare limits on physician fees for specific services; (4) beneficiaries unaware of appeal decisions made by Medicare carriers on their claims; and (5) beneficiaries unaware of Medicare paying for second opinions.

Current Law/Policy

This is the fourth survey the OIG has conducted to determine beneficiary experience and satisfaction with Medicare services.

The HCFA should develop a plan for improving beneficiary satisfaction and understanding in the trouble areas mentioned above.

Status

Management Response

The HCFA has developed initiatives such as, emphasizing community outreach activities and greater reliance on HCFA's partners to disseminate information. The HCFA is working with a contractor to assess current publications clearinghouse activities and suggest improvements, due in early 1997. The HCFA is disseminating all beneficiary publications in English and Spanish on the Internet.

Educate Medicare Beneficiaries About Managed Care Options

Report Number:	OEI-04-93-00142	Final Report:	10/95	
Finding				
	receptive to the increas mation regarding their b	•	n maintenance organization ability.	ons (HMO) and
Current La	w/Policy			
arrangement. Ho			n medical care through a y also have the option to i	
Recommer	ndation	Legislative	✓ Administrative	Material Weakness
managed care op where HMOs are	otions and HMOs. The	HCFA should: (aries can join; ar	cate Medicare beneficiario (1) focus its educational end (2) highlight characterient procedures.	efforts in areas
Status				
Management R	lesponse			
The Balanced B	udget Act of 1997 man	dates HCFA to p	provide extensive Medicar	re health plan

The Balanced Budget Act of 1997 mandates HCFA to provide extensive Medicare health plan information, including comparative information for managed care plans (cost benefit, HEDIS/CAHPS, disenrollments future), in print and distribute this information to all current beneficiaries on a yearly basis. Medicare & You 2000, which will be mailed to 34 million beneficiary households in the fall of 1999, contains basic comparison information. A variety of support publications have been developed to assist beneficiaries in decision making, including a worksheet for comparing Medicare Health Plans.

Improve Beneficiary Understanding of Home Health Services

Report Number: OEI-04-93-00143 Final Report: 11/95
Finding
Most beneficiaries are satisfied with home health care, but about half do not understand what has been paid by Medicare.
Current Law/Policy
Medicare pays for home health care delivered to beneficiaries who are homebound and in need of skilled services. Because there is no coinsurance for this service, no explanation of benefits is mailed to beneficiaries.
Recommendation Legislative Administrative Material Weakness
The HCFA should continue to build upon its efforts to improve beneficiary understanding of the home health benefit.
Status
Management Response

The HCFA concurs. The HCFA distributed a pamphlet and video tape explaining the home health benefits. In 1996, all Medicare beneficiaries received a copy of the Medicare handbook containing an explanation of home health benefits.

Review the Impact of OBRA 1990 on State Regulation of Medigap Insurance

Report Number: OEI-09-93-00230 Final Report: 3/95

Finding

Implementation of 1990 Medigap reforms has substantially improved State regulations of Medigap insurance.

Most respondents believe the Federal/State collaboration to implement OBRA 1990 was effective.

Current Law/Policy

Medicare covers about 75 percent of the actual cost of medical care provided to beneficiaries. Beneficiaries are responsible for deductibles and coinsurance amounts under Part A (hospital insurance) and Part B (supplemental medical insurance), as well as services and items that Medicare does not cover. Medicare beneficiaries have private health insurance including Medicare supplemental, or "Medigap" to cover some of their expenses.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

We recommended that HCFA: (1) implement plans for direct regional office assistance to information, counseling, and assistance grantees; (2) consider expanding the Complaints Data Base System to reflect received, closed, and pending Medigap complaints; direct State insurance departments (SIDs) to furnish key required data, such as policy type, for each reporting period; clarify instructions to assure uniform reporting of data by States; and (3) work with the National Association of Insurance Commissioners and SIDs to encourage States to adopt consumer safeguards exceeding the minimum standards, including open enrollment for the disabled and community rating of premiums.

Status

Management Response

The HCFA concurs with the first recommendation. The HCFA regional offices continues to build partnerships with Insurance Counseling Agency (ICA) grantees and provide technical assistance and training. The HCFA regional offices are working closely with the ICA grantees, PROs, carriers and intermediaries, the Social Security Administration, and the State and local agencies on aging.

The HCFA continues to noncur with recommendation two and is reevaluating recommendation three by giving further consideration to the issues of open enrollment for the disabled and premiums.

Consider Recommended Safeguards Over Medicaid Managed Care **Programs**

Final Report: Report Number: OAS-03-93-00200 8/93 **Finding**

Current Law/Policy

reduce the risk of insolvency and to protect Federal funds.

Medicaid regulations allow States to impose solvency requirements on contracting managed care plans.

We found that there is a need for improved safeguards over Medicaid managed care programs to

Recommendation	Legislative	A dministrative	Material Weakness

The HCFA should consider several safeguards available to reduce the risk of insolvency and to ensure consistent and uniform State oversight. Specifically, we recommended that HCFA (1) use Medicare solvency guidelines, (2) establish minimum net worth standards, (3) develop a financial data base to measure the financial operations of managed care plans, (4) establish time frames in which to apply sanctions against poorly performing managed care plans, (5) mandate the use of a medical escrow account, (6) require that reinsurance plans be State approved and based on actuarial studies, (7) require State review of all third party transactions, (8) develop excess profit criteria, and (9) require State audits of managed care plans.

Status

Management Response

The HCFA concurred with recommendations 1 through 4. However, the Balanced Budget Act of 1997, Section 4706, requires managed care organizations to meet only the solvency standards established by the State for private HMOs. Recommendations 5 through 9 remain unresolved. The HCFA commented that the findings were of limited value because the report was based on examination of only two plans and that a broader analysis of managed care programs would be needed to identify shortcomings common to many Medicaid managed care plans and to make broad program recommendations. We disagree. The concerns raised in our report have also been expressed by the Congress and the General Accounting Office. We do not believe HCFA should wait for a detailed study before taking a more aggressive role in protecting Federal and State funds. We are continuing our reviews of Medicaid managed care plans.

Retooling Medicaid Agencies for Managed Care

Report Number: OEI-01-95-00260 Final Report: 8/97

Finding

We have identified five major organizational challenges faced by Medicaid agencies. The organizational challenges are (1) establishing core development teams; (2) acquiring necessary knowledge and skills; (3) instilling a new mission and culture; (4) redeploying fee-for-service staff; and (5) avoiding a fee-for-service meltdown.

Current Law/Policy

The movement to enroll Medicaid beneficiaries in managed care began in the early 1980s, as States experienced fiscal pressures due to rising Medicaid costs. Over the past 15 years, States have increasingly used managed care to provide medical services for Medicaid beneficiaries. States have primarily enrolled adults and children in low-income families into managed care, whereas aged for disabled beneficiaries remain under fee-for-service systems. By 1996, over 500 managed care organizations were providing services to 13 million Medicaid beneficiaries.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

The HCFA should: (1) provide forums to help State Medicaid managers take advantage of the opportunities managed care present for retooling their agencies and to minimize the associate dangers; (2) revise its review and monitoring protocols so that they devote greater attention to how State Medicaid agencies are handling the organizational challenges associated with expanded managed care; and (3) scrutinize possible adverse effects of managed care expansion on the performance of established fee-for-service functions.

Status

Management Response

The HCFA concurred with our recommendations. On an ongoing basis HCFA subsidizes the American Public Human Services Association meetings that address Medicaid managed care and the challenges it poses. However, HCFA reports that most efforts are currently focused on implementing provisions of BBA of 1997 rather than focus on how State Medicaid agencies are organized to address expanded managed care.

Use Beneficiary Surveys As A Protection Tool for Medicaid Managed Care

Report Number: OEI-01-95-00280 Final Report: 5/97

Finding

We found that (1) surveys provide little useful information about plan performance to Medicaid agencies;(2) the surveys have yet to provide beneficiaries with information to help them choose a plan; (3) both agencies and plans face basic hurdles in surveying the Medicaid population; (4) some agencies are beginning to use surveys in strategic ways, with potentially promising results; and (5) notwithstanding the limitations of beneficiary surveys, heatlh plans still find them to be of some use in identifying and responding to enrollee concerns.

Current Law/Policy

Over the past 15 years, States have increasingly used managed care to provide medical services to Medicaid beneficiaries. States are allowed more flexibility in delivering managed care through the freedom-of-choice 1915b waiver or the 1115 waiver. The Health Care Financing Administration often requires Medicaid agencies implementing managed care waivers to conduct surveys.

The HCFA should either establish a work group or technical advisory group on Medicaid beneficiary surveys or add to the agenda of an existing group. Either group should provide policy-level guidance on how to make cost-effective use of beneficiary surveys.

The HCFA should devote greater attention to how the Medicaid agencies are using beneficiary surveys. It should revise its written guides for reviewing and monitoring Medicaid managed care initiatives to call attention to the importance of using beneficiary surveys in more focused, strategic ways.

Status

Management Response

The HCFA partially concurred with recommendation one. The HCFA stated that its existing Medicaid Managed Care Technical Advisory Group has a work group currently working on consumer information and surveys. The HCFA is also collaborating with the Agency for Health Care Policy and Research, which is leading the Consumer Assessment of Health Plans Study. The HCFA agreed with our assessment that agencies often conduct surveys for multiple purposes but disagreed with our assessment that these were often of limited value.

The HCFA concurred with our second recommendation and plans to include a special session on survey development and use of survey data in its annual Managed Care College and will stress the importance of surveys in its technical assistance to HCFA regional offices and State Medicaid staff.

Coordinate Medicaid Managed Care Plans with HIV/AIDS Services

Report Number: OEI-05-97-00210 Final Report: 4/98

Finding

We found that: (1) Medicaid managed care organizations (MCOs) that are paid an AIDS-enhanced rate appear to provide all needed medical services and drugs to AIDS patients. The MCOs that are not paid an enhanced rate report they cannot afford to continue providing these services and drugs without adequate financial compensation. (2) In States visited, the Medicaid managed care and Ryan White programs do not coordinate the services they provide to persons with HIV/AIDS.

Current Law/Policy

Under Medicaid, States may choose to exercise any of several options to pay for care for beneficiaries with AIDS, including: pay MCOs an AIDS-enhanced rate, carve-out AIDS patients from managed care, put all AIDS patients in a specified MCO or put them into the same insurance pool with all Medicaid beneficiaries. There is no Federal requirement that the Medicaid and Ryan White programs coordinate services. Some States have made this a requirement of both programs, many have not.

The HCFA should: (1) In consultation with HRSA, develop and disseminate technical assistance and guidance on strategies State Medicaid programs can use to establish appropriate managed care contracts for needed medical services and costs related to these services for beneficiaries with HIV and AIDS. (2) Urge States to require Medicaid managed care plans to coordinate with Ryan White programs on the services they provide to Medicaid beneficiaries with HIV/AIDS. The HRSA should continue to encourage Ryan White grantees to work with Medicaid managed care plans. Together, these agencies should work to develop strategies of coordination for Medicaid managed care and the Ryan White programs.

Status

Management Response

(1) The HCFA concurred with both of our recommendations and is interested in developing guidance providing information about the needs of persons with HIV/AIDS, and the likely gaps in services provided under managed care. They are also interested in developing a State-by-State analysis of cost estimates, however, those costs need to be made available to HCFA by the States. The HCFA encourages State Medicaid agencies to actively participate in any coordination between MCOs and Ryan White programs and in describing which services should be provided by Medicaid through the MCOs or fee-for-service. (2) The HRSA concurred with our recommendation regarding coordination between State Medicaid and Ryan White programs. They are involved in a pilot managed care training and technical assistance program to improve the capabilities of Ryan White programs to participate in managed care projects, expanding their efforts in providing managed care technical assistance on-site and, are involved in multi-State demonstrations designed to improve the collaboration between Medicaid MCOs and Ryan White programs. Additionally, HHS' Managed Care Forum AIDS Workgroup co-chaired by staff from HCFA and HRSA, agreed to begin development of technical assistance strategies to improve coordination between the two programs.

Improve Relationship Between Physician and Beneficiary When Ordering Medicare Equipment and Supplies

Report Number: OEI-02-97-00080 Final Report: 2/99

OEI-02-97-00081 2/99

Finding

We found that two-thirds of physicians are satisfied with the current process of ordering medical equipment and supplies. Physicians who are more informed about Medicare requirements for coverage and payment of medical equipment and supplies are more likely to be satisfied with the ordering process. Most medical equipment and supplies are prescribed by the treating physician, but in 6 percent of the cases the physician reported not knowing the patient and 13 percent of physicians who say they knew the patient did not order the equipment or supplies. Fourteen percent of sample medical equipment and supplies were either questionable or medically unnecessary, which represents \$414 million in inappropriate Medicare payments.

Current Law/Policy

Medicare recognizes the physician as the key figure in determining the appropriate utilization of medical services. As one component of this process, Medicare requires that payment for certain non-physician services, such as home health agency, therapy and diagnostic services, as well as medical equipment and supplies, are conditional on the existence of a physician's order. According to Medicare regulation 42 CFR Section 424, the provider of these services is generally responsible for obtaining the required physician certification and re-certification statements, and for keeping them on file for verification.

Recommendation	egislative V	Administrative	Material Weakness
----------------	---------------------	----------------	-------------------

The HCFA should: (1) strengthen its efforts to educate physicians regarding their ordering of medical equipment and supplies; and (2) ensure that the physician who orders the equipment or supplies is required to treat the patient prior to the order and a systematic process is developed to assure that the supplier submits a new CMN or order to the durable medical equipment regional carriers (DMERC) when the physician changes the equipment or supply, or the medical need for the equipment or supply changes; and that the referring physician's name and specialty and the patient's related diagnostic information are required on all claims for medical equipment and supplies.

Status

Management Response

The HCFA generally concurs with our recommendations. The HCFA believes there should be a relationship between the physician and beneficiary before a durable medical equipment (DME) item is ordered. The DMERCs are currently taking steps to educate all participating physicians with information about ordering medical supplies and equipment. The DMERCs are currently accomplishing this goal via a number of vehicles such as articles in carrier bulletins and presentations at carrier advisory committee meetings, national work groups, and consortia conferences. As part of this effort, the DMERC Summer 1999 Provider Bulletins contain information regarding ordering DME and the relationship between physicians and beneficiaries.

Prevent Inappropriate Medicaid Payments for Incontinence Supplies

Report Number: OEI-03-94-00771 Final Report: 11/95

Finding

Our report found that Medicaid is vulnerable to questionable billing practices for incontinence supplies. In one State, California, improper payments exceeded \$100 million. Other States experienced problems, but to a lesser degree. We also found that States do not generally review the appropriateness or necessity of incontinence services paid by Medicare, and that Medicare does not require contractors to notify Medicaid State agencies of improper crossover payments made on behalf of Medicaid beneficiaries. Thus, States may inadvertently make unallowable payments for Medicare.

Current Law/Policy

Under the Medicaid program, States have the option to cover incontinence care supplies and related equipment. Based on prescriptions furnished by patient's physicians, such supplies and equipment could include disposable pads, irrigation syringes, saline solutions, and collection devices.

Legislative Administrative Material Weakno	Recommendation	Legislative	A dministrative	Material Weakne
Naudillia il Gillul and a legislative in Administrative in Material Weakn	Recommendation	I egislative	Administrative	Material Weakn

The HCFA should: (1) alert Medicaid State agencies about the vulnerability regarding incontinence supplies; and (2) take appropriate steps to ensure that Medicaid State agencies are notified of improper Medicare payments which contractors discover have been made on behalf of Medicaid beneficiaries.

Status

Management Response

The HCFA concurs with the recommendations. The HCFA sent a fraud alert to all Medicaid State agencies regarding inappropriate billing for incontinence devices. The HCFA plans to amend the Medicare Carriers Manual to require that carriers notify Medicaid State agencies about improper payments made on behalf of Medicaid recipients.

5/96

Ensure Appropriate Mental Health Services Delivered in Nursing Homes

Final Report:

Report Number: OEI-02-91-00860

Finding A review of nursing home medical records revealed a series of problems in the delivery of mental health services to patients in nursing homes, including (1) not receiving needed care; and (2) lesser skilled individuals providing services. [See also information in our Cost-Saver Handbook concerning the opposite problem, dollars lost due to inappropriate care being delivered.] **Current Law/Policy** Medicare covers mental health services delivered to beneficiaries, subject to a 20 percent coinsurance by beneficiaries. Such services are covered when medically necessary and rendered by a psychiatrist, clinical social worker, or psychologist. Recommendation Legislative Administrative Material Weakness The HCFA should take a series of steps to ensure appropriate services are delivered, including educational activities and guidelines. **Status Management Response**

The HCFA concurs with the recommendation. The HCFA is taking steps to ensure appropriate services are delivered. The HCFA is developing a final rule for coverage of clinical psychological services. The Carriers Medical Directors workgroup developed and distributed a final model medical review policy to address Medicare coverage of psychiatry and psychology services. While the model policy is not HCFA's national policy, it is available to all carriers to use in developing their own local policies. A final rule for coverage of clinical psychological services is pending.

Orange Book 1998-99 Nursing Homes Page 32 of 93

Improve Nursing Home Surveyor Staffing and Training

Report Number: OEI-02-98-00330 Final Report: 3/99

Finding

We found that nursing home surveyor staffing may be inadequate to conduct follow-up surveys and to respond to complaints. In addition, we found that while new surveyor training is consistent across our sample States, ongoing training for surveyors ranges from no training to 100 hours per year.

Current Law/Policy

Nursing home surveyors are required to complete mandatory standard surveys of each nursing home approximately annually. Surveyors are also responsible for surveying nursing homes when complaints are generated or when follow-up visits are required for nursing homes with deficiencies. All State surveyors complete Federal training in HCFA headquarters in order to pass the required Standard Minimum Qualifications Test.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

We recommended that HCFA: (1) Evaluate the surveyor staffing in each State to assure that adequate staffing is available to complete all standard surveys, follow up surveys, and respond to complaints. (2) Provide additional training to State surveyors.

Status

Management Response

In comments to the draft report, HCFA concurred with our recommendations. The HCFA indicated that it reviews State surveyor staffing as part of the survey and certification budget process. The HCFA will be examining these data more closely as part of the effort to determine whether States are complying with the requirements of the contractual agreement they enter into with HCFA to perform survey activities. The HCFA also indicated that the issue of training was being addressed by the new Federal Monitoring System and that feedback from the States on that system will guide training and coordination efforts.

Develop Nurse Staffing Standards for Nursing Homes

Report Number: OEI-02-98-00331 Final Report: 3/99 **Finding** We found that many of the most frequently cited nursing home deficiencies are directly related to reported shortage of direct care staff. The failure to provide proper treatment to prevent or treat pressure sores illustrates the lack of direct care staff to assure that residents are properly hydrated, nourished, and turned frequently. **Current Law/Policy** The Omnibus Budget Reconciliation Act of 1987 requires nursing facilities to have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. Recommendation Legislative Administrative Material Weakness We recommend that HCFA develop staffing standards for registered nurses and certified nurse assistants in nursing homes to assure sufficient staff on all shifts and to enable residents with proper care. Staffing standards should account for the intensity of care needed, qualifications of the staff, and the specific characteristics of both the nursing home and the residents.

Status

Management Response

The HCFA has awarded a contract to conduct a comprehensive nurse staffing study. The HCFA plans to submit this study to Congress by the end of 1999.

Improve Dissemination of Nursing Home and Medigap Guides

Report Number:	OEI-04-92-00481	Final Report:	5/94	
Finding				
soliciting a nursing	ng home and supplement. Most beneficiaries st	ntal health policies	ets developed to assist beness. Beneficiaries who used to use the booklets if they nee	the booklets
Current Lav	w/Policy			
•	shed two booklets to guardence to supplement Med		eficiaries in selecting a nur	rsing home
Recommen	ndation	Legislative	A dministrative	Material Weakness
		•	stration and the Office of the rategy to make the booklet	
Status				

Management Response

The HCFA has developed initiatives such as, emphasizing community outreach activities and greater reliance on HCFA's partners to disseminate information. The HCFA is working with a contractor to assess current publications clearinghouse activities and suggest improvements. The contractor will be issuing final reports with recommendations for improvements and solutions. The HCFA is disseminating all beneficiary publications in English and Spanish on the Internet.

Orange Book 1998-99 Nursing Homes Page 35 of 93

Improve Medicaid Estate Recovery Programs

Report Number: OEI-07-92-00880 Final Report: 3/95 **Finding** At the time of the survey (October 1993), 27 States had established estate recovery programs. **Current Law/Policy** The Omnibus Budget Reconciliation Act of 1993 required States to establish Medicaid estate recovery programs, effective October 1, 1993. Recommendation Legislative Administrative Material Weakness The HCFA should develop performance indicators to track States' progress in implementing the OBRA '93 requirement. This would aid in identifying States with particular problems, establish expectations and a method for benchmarking progress, and yet allow States flexibility in finally choosing the mix of tools to achieve expected results. **Status Management Response**

The HCFA concurs. The HCFA drafted a national performance standard which was under review; however, they have abandoned their efforts.

(Continued 2)

Report Number: OEI-07-92-00880 Final Report: 3/95

Finding

Existing Medicaid estate recovery programs provide lessons on operational challenges. These operational challenges include: (a) Obtaining State enabling legislation. Forty of the 50 States require authorizing or confirming legislation to implement the OBRA '93 mandatory requirements. (b) Insufficient resources and limited staffing. Few States are able to budget for recovery program staff on a fulltime basis, most devote one-third to one-half of their time to estate recovery. (c) Reluctance to use lien recovery authority granted under TEFRA of 1982. Only 14 States file liens on property, six States utilize TEFRA liens. (d) Detecting out-of-State assets. States say they have limited capabilities to determine and verify the existence and amount of a Medicaid recipient's out-of-State assets. (e) Recovery from surviving spouse estates. Only 10 States pursue recoveries from the estate of the surviving spouse. States cite many difficulties in tracking the death of a surviving spouse.

Current Law/Policy

The Omnibus Budget Reconciliation Act (OBRA) of 1993 required States to establish Medicaid estate recovery programs, effective October 1, 1993. The programs may be developed in any manner that is approved by each State. The law permits a delayed compliance date for States requiring authorizing or conforming State legislation.

Recommendation Leg	rislative	Administrative	Material Weakness
--------------------	-----------	----------------	-------------------

The HCFA should (1) target mechanisms for recovery that have high dollar payoff and identify strategies to help make necessary information available to State agencies to pursue those mechanisms; and (2) closely monitor States' progress in obtaining enabling legislation and pursue legislative authority to impose sanctions or penalties if States do not act within a reasonable period of time to implement OBRA '93.

Status

Management Response

The HCFA concurs with our recommendations and has issued compliance letters to 12 States. A Technical Advisory Group on Third Party Liability is developing strategies for implementing this recommendation.

Orange Book 1998-99 Nursing Homes Page 37 of 93

Assess Vulnerabilities in Medicaid Asset Verification

Report Number: OEI-07-92-00882 Final Report: 10/95

Finding

Most States rely only on readily available sources for asset verification. Nearly all States verify checking and savings accounts, paystubs and insurance policies, but States vary on requesting income tax returns and other types of financial information.

Efforts to identify and combat Medicaid fraud vary among States. Forty percent of States do not have Medicaid fraud hotlines and 24 percent of States do not have specific Medicaid long term care fraud penalties for the non-reporting resources.

The HCFA has worked in partnership with State Medicaid agencies to improve asset verification.

Current Law/Policy

Eligibility for Medicaid long term care coverage is based on an individual's income and assets. Individuals with substantial assets who need long term care may be motivated to transfer their assets to other family members or friends. Such transfers create artificial poverty in order that individuals may finance their nursing home expenses through the Medicaid program. Each State has its own rules and provisions governing Medicaid long term care eligibility.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

The HCFA should continue to work in partnership with States to promote:

- Comprehensive asset verification technique
- Establishment of Medicaid fraud hotlines and penaltie
- Identification and sharing of useful best practices among State

Status

Management Response

The HCFA concurs with our recommendations.

An Income Eligibility Verification Systems (IEVS) interagency workgroup was developed to oversee the State operation of IEVS. Prior to any future changes, the workgroup will need to consider the impact of welfare reform.

Orange Book 1998-99 Nursing Homes Page 38 of 93

Ensure Equal Distribution of Organs for Transplantation

Report Number:	OEI-01-89-00550	Final Report:	3/91

Finding

In a number of important respects, current organ distribution practices fall short of congressional and professional expectations. Clear documentation shows unequal access to kidney transplants among the races, even when blood type, age, immunological, and locational factors are taken into account.

Current Law/Policy

The statute requires that organs should be distributed equitably among awaiting patients. Implementation of this requirement has drifted toward distribution among organ procurement organizations rather than patients.

Recommendation	I agiclativa	Administrative	Material Weakness
Recommendation	Legislative	A dministrative	Material Weaknes

Before HCFA grants certification to organ procurement organizations (OPOs) it should ensure, in collaboration with PHS, that the OPOs are: (1) distributing organs equitably among patients, according to established medical criteria; and (2) conducting a rigorous soundly-based organ procurement effort.

The HCFA and PHS should support a research agenda that facilitates the elimination of racial disparities in organ allocation.

Status

Management Response

The HCFA concurred with these recommendations. The HCFA issued regulations regarding certification of OPOs, but PHS has yet to issue regulations regarding organ sharing among patients. The HCFA is continuing to use information received from PHS to make decisions regarding procurement performance standards. In 1996, HCFA conducted the first organ procurement organization (OPO) recertification cycle using its new performance standards. Two OPOs were terminated due to poor performance. The Secretary conducted public hearings on distribution of livers in December 1996. One organ procurement organization is being terminated as a result of the 1998 recertification process.

Improve Medicare's Oversight of Managed Care Plan Performance

Report Number: OEI-01-96-00190 Final Report: 4/98

Finding

Our report found that (1) HCFA's primary oversight approach--a site visit that relies on a rigid monitoring protocol--has fundamental limitations as a way of overseeing managed care plans' performance; (2) overall, HCFA is not taking widespread advantage of available data that coould be used for ongoing, systematic oversight of plans; and (3) that HCFA is missing opportunities to capture additional data that could assist the agency in monitoring plans' performance.

Current Law/Policy

The HCFA is responsible for ensuring quality of and access to care provided to Medicare beneficiaries and for safeguarding the program from fraud and abuse. Medicare supports two primary types of managed care plans, fee-for-service and capitation plans.

Recommendation	Legislative	✓ Administrative	Material Weakness

The HCFA should: (a) revise the processes that it uses to monitor the performance of managed care plans; and (b) take better advantage of data that are currently available to the agency as a way of monitoring plan performance on an ongoing basis.

Status

Management Response

The HCFA concurs with the intent of all the recommendations. The HCFA is revising the current monitoring process by evaluating changes to the methods of evaluation and devising better methods for targeting performance issues within health plans. On a larger scale, HCFA has implemented the Health Plan Monitoring System (HPMS). When fully functional, this new system will consolidate data obtained from monitoring reviews, enrollment and disenrollment, reconsideration, performance measures from the Health Plan Employer Data and Information Set, and the national Medicare beneficiary satisfaction survey from the Consumer Assessment of Health Plans Study. Finally, HCFA has designed a computer system to receive, track, and report beneficiary inquiries. The HCFA will use this system as soon as programming is complete and the overall system is in place. An initial implementation of the HPMS monitoring protocol function will be available in FY 2000.

Ensure Expertise in HCFA Staff for Managed Care Oversight

Report Number: OEI-01-96-00191 Final Report: 4/98

Finding

We found that HCFA regional offices made a strong commitment to increase staffing for managed care oversight. However, the vast majority of the new staff lack experience with managed care. We also found that managed care units in many regional offices lack staff with specialized backgrounds that could enhance oversight of managed care plans.

Current Law/Policy

The HCFA is responsible for ensuring quality of and access to care provided to Medicare beneficiaries and for safeguarding the program from fraud and abuse. Medicare supports two primary types of managed care plans, fee-for-service and capitation plans.

Recommendation	Legislative	A dministrative	Material Weaknes

(1) The HCFA should develop, coordinate, and provide a comprehensive training program for regional office staff with responsibility for oversight of managed care plans. (2) As HCFA increases staff in its managed care operations in the regional offices, we recomend that the agency seek out people with experience in managed care, data analysis, and clinical expertise. (3) We also recommend that HCFA develop a pilot program to provide opportunities for staff development and staff sharing with managed care plans and beneficiary advocacy groups.

Status

Management Response

The HCFA agrees with the intent of developing a pilot program to provide opportunities for staff development and staff sharing with managed care plans and with beneficiary advocacy groups. However, they are concerned that confidential information for current contacting plans and new applicants should not be accessible to non-Federal employees who are working as HCFA staff.

The HCFA continues to work on improving its methods for training. A new training team comprised of staff is developing training modules for staff of varying degrees of expertise. This training team is also exploring various methods of training, e.g. satellite broadcasts, mentoring, and workshops.

Over the past several years HCFA has been successful in recruiting new staff with expertise with some of the skill sets identified by the OIG. The HCFA has hired new employees who have worked for managed care organizations, clinicians, and staff with specific data analysis skills.

Improve Hospital Discharge Planning for Beneficiaries

Report Number: OEI-02-94-00320 Final Report: 5/97

Finding

We found that hospital ownership: (1) seems to have little influence on which nursing home patients are referred, however, it does influence the length of stay in both the hospital and the nursing home; (2) seems to have influence on which home health agency patients are referred; (3) influences the duration of home health agency services; (4) benefiaries who go to hospital-owned nursing homes and home health agencies report better continuity of care; and (5) does not impact beneficiaries' level of satisifaction.

Current Law/Policy

Federal regulation 42 CFR, Section 482.43, effective January 12, 1995, requires that hospitals have in place a discharge planning process. This process must apply not only to Medicare and Medicaid patients, but to all patients served by the hospital who need discharge planning.

Recommendation	✓ Legislative	✓ Administrative	Material Weakness

We recommend that HCFA: (1) assure that hospitals disclose ownership of home health agencies and nursing homes in a systematic way; and (2) take additional measures to assure that when beneficiaries are being discharged from the hospital they are given a choice in selecting a home health agency or nursing home from which to receive care.

Status

Management Response

The Balanced Budget Act of 1997 addresses the concern that hospitals disclose ownership information and that Medicare beneficiaries are informed of their freedom to choose the home health agency or nursing home to which they will be referred.

The HCFA is in the process of implementing this new provision.

Assess Beneficiaries' Experiences with and Satisfaction with Medicare Services

Report Number: OEI-04-97-00030 Final Report: 6/98

Finding

In our report, we found: (1) as in 1995, beneficiaries report positive experience with the Medicare program; (2) beneficiary awareness of one service improved from 1995 to 1997; (3) beneficiary awareness of some services declined; (4) some services needed improvement in 1995, and still do in 1997; and (5) beneficiary awareness of some services not reported on in 1995 was found to be lacking in 1997.

Current Law/Policy

Medicare is a Federal health insurance program for individuals age 65 and older, and for certain categories of disabled people. The HCFA has responsibility for the Medicare program. However, other organizations share program administration. The Social Security Administration establishes eligibility, enrolls beneficiaries in the program, and collects Medicare premiums. Private health insurance companies contract with the Federal Government to service claims for Medicare payment.

We recommend that HCFA develop a plan for improving beneficiary satisfaction and understanding in the trouble areas mentioned in this report. We suggest that in planning corrective actions, HCFA set numerical goals that can be tracked for program improvement.

Status

Management Response

The HCFA concurred with our recommendation. The HCFA has initiated a National Medicare Education Program that will use multidimensional strategies to assist beneficiaries in making informed health care decisions. Further, HCFA will provide access to program information via the Internet and an updated Medicare Handbook.

Improve Controls to Monitor Chiropractic Care

Report Number: OEI-04-97-00490 Final Report: 9/98

Finding

We found that Medicare, Medicaid, and private insurers rely on utilization caps, x-rays, physician referrals, co-payments, and pre and post payment review, in varying degrees, to control utilization of chiropractic benefits. Utilization caps are the most widely used, but these and other controls did not detect or prevent unauthorized Medicare maintenance treatments.

Current Law/Policy

In 1972, Section 273 of the Social Security Amendment (P.L. 92-603) expanded the definition of physician under Part B of Medicare to include chiropractors. Currently, the only Medicare reimbursable chiropractic treatment is manual manipulation of the spine to correct a subluxation demonstrated by an x-ray. When chiropractors were recognized as physicians and became eligible to participate in Medicare in 1972, chiropractors also became eligible to participate in Medicaid. Under Medicaid, however, chiropractic services are not a mandatory benefit, but rather an optional service. According to Federal policy for Medicaid, chiropractic services should be limited to manual manipulation of the spine and x-ray services. The Balance Budget Act of 1997 required HCFA to establish new utilization guidelines for Medicare chiropractic care by January 1, 2000. It also eliminated the x-ray requirement.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

The HCFA should develop system edits to detect and prevent unauthorized payments for chiropractic maintenance treatments. Examples include: (1) requiring chiropractic physicians to use modifiers to distinguish the categories of the spinal joint problems, and (2) requiring all Medicare contractors to implement system utilization frequency edits to identify beneficiaries receiving consecutive months of minimal therapy.

Status

Management Response

The HCFA staff concurred with our recommendations, however, implementation is delayed due to contractors Year 2000 systems issues.

Ensure Children in Medicaid Managed Care Receive Timely EPSDT Services

Report Number: OEI-05-93-00290 Final Report: 5/97

Finding

In our report we found (1) fewer than one in three Medicaid children enrolled in managed care plans receive timely EPSDT services. Six of 10 receive none at all; and (2) children receive significantly more EPSDT services from Medicaid managed care plans when States inform the managed care plans which children are due for EPSDT.

Current Law/Policy

Under EPSDT, State Medicaid agencies must provide eligible children services that include comprehensive, periodic health assessments beginning at birth and continuing through age 20. All medically appropriate immunizations are required. Age appropriate assessments must be provided at intervals following defined periodicity schedules. State Medicaid agencies have turned to managed care to rein in escalating health care costs, difficult to in a fee-for-service environment, while ensuring health care access for Medicaid enrollees.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

The HCFA should (1) revise its EPSDT reporting requirements and data collection to emphasize the number of children who receive all of their EPSDT screens in a timely fashion; (2) encourage States to actively notify managed care plans of enrollees due for EPSDT exams and to follow up if EPSDT services are not rendered shortly thereafter; (3) work with States to ensure timely managed care EPSDT reporting; and (4) emphasize to States the need to define and clarify EPSDT requirements in its Medicaid contracts with managed care plans.

Status

Management Response

The HCFA concurred with our recommendations. The HCFA has developed a work group comprised of representatives from the public and private sectors to assess and recommend changes to the current EPSDT reporting and data collection tool. The HCFA will continue to encourage States through its review and approval of new and existing waivers to include specific EPSDT programmatic requirements in their contracts with managed care programs.

Improve Oversight of the Rural Health Clinics

Report Number: OEI-05-94-00040 Final Report: 7/96

Finding

Rural health clinics and associated Medicare and Medicaid expenditures have grown substantially since 1990. Four interrelated factors appear to be driving the recent growth of rural health clinics: providing access to care, reimbursement, managed care, and the certification process.

Rural health clinics may be increasing access to care in some areas but not in others.

Rural health clinics are paid based on their costs, which may be inflated or inappropriate but are difficult and sometimes impossible to verify or audit without significant resource expenditure by the Government.

Current Law/Policy

The Rural Health Clinic program created in 1977 by Public Law 95-210 is intended to increase access to health care for rural medically underserved areas and to expand the use of midlevel practitioners in rural communities.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

The HCFA, along with the Health Resources and Services Administration, should modify the certification process to increase State involvement and ensure more strategic placement of rural health clinics.

The HCFA should expedite the issuance of the regulations now under development.

The HCFA should take immediate steps to improve the oversight and functioning of the current cost reimbursement system, with a long term goal of implementing a different method.

Status

Management Response

The HCFA concurs with the intent of our recommendations. The Balanced Budget Act of 1997 refines the requirements for rural health clinic designations, and provider-based reimbursement. The HCFA developed a program memorandum consolidating and clarifing the policy regarding provider-based and free-standing designation decisions. The HCFA is expected to issue proposed regulations on Balanced Budget Act changes to the rural health clinics program, designed to control program growth.

Improve Oversight of the Medicare Risk HMO Program

Report Number: OEI-06-95-00430 Final Report: 3/98

Finding

We found overall beneficiaries in Medicare risk health maintenance organizations (HMOs) gave a favorable report of good service access in 1996. Some problems we reported in 1993 have substantially improved. Some reported problems continued in 1996, however, and some new ones have surfaced. The more vulnerable Medicare beneficiaries in HMOs--the functionally limited, disabled, and chronically ill--experienced more service access problems.

Current Law/Policy

The HCFA has oversight responsibility for Medicare risk contracts with HMOs. Under a risk contract, Medicare pays the HMO a predetermined monthly amount per enrolled beneficiary. Once enrolled, beneficiaries are usually required to use HMO physicians and hospitals, and obtain prior approval from their primary care physicians for other primary care.

Recommendation	Legislative	Administrative	Material Weakness
rtocommicmation	Legislative	Aummsuauve	Iviateriai vy cakriess

We continue to believe HCFA needs to improve its oversight of the Medicare risk HMO program in six persistent areas: (1) assuring HMOs properly inform beneficiaries about their appeal and grievance rights; (2) improving beneficiaries' understanding of HMO procedures and restrictions for obtaining services; (3) preventing inappropriate screening of beneficiaries' health status at application; identifying and carefully monitoring service access problems encountered by functionally limited, disabled, and chronically ill beneficiaries; (4) systematically collecting and tracking over time HMO-specified beneficiary-reported data on access to medical services and reasons for disenrollment; and (5) distinguishing between administrative and non-administrative disenrollments, if HMO disenrollment rates are to be used as a performance indicator.

Status

Management Response

The HCFA concurs with the recommendations. The HCFA is striving to improve beneficiary outreach and education to make them aware of their appeal and grievance rights. The HCFA has developed a Medicare managed care data base to assist in improving beneficiaries' understanding of procedures and restrictions within managed care plans. In addition, HCFA's Quality Improvement System for Managed Care and the Health of Seniors component of the Health Plan Employer Data and Information Set will help assess whether Medicare beneficiaries believe they receive adequate access to health care services.

Finally, HCFA plans to address the concerns raised in this OIG report. The disenrollment reasons will be addressed in a disenrollment survey conducted by HCFA.

Address Problems Identified by Beneficiaries in Medicare Risk HMOs

Report Number: OEI-06-95-00434 Final Report: 8/98

Finding

We found significant differences between these vulnerable beneficiaries and their healthier counterparts regarding their experiences with enrollment, access to services, care from their primary doctors, and difficulty of obtaining health maintenance organization (HMO) care. Specifically, functionally limited, comorbid and disabled beneficiaries experienced more problems in accessing services than healthier beneficiaries, particularly specialized services; vulnerable beneficiaries found it hard to obtain care through their HMO; while able to obtain timely appointments when they were very ill, vulnerable beneficiaries were more critical of the care received from their primary physicians; and a sizable proportion of vulnerable enrollees said that while their health improved, about one-fifth of vulnerable disenrollees were more likely than less impaired groups to have been inappropriately asked about their health problems when applying to their HMO.

Current Law/Policy

Medicare beneficiaries may join a risk HMO or remain in the fee-for-service program. When enrolling beneficiaries, the HMO may not deny or discourage enrollment based on a beneficiary's health status except for end-stage renal disease or hospice care. The HMO must also adequately inform beneficiaries about lock-in to the HMO and appeal and grievance procedures. Once enrolled, beneficiaries are usually required to use HMO physicians and hospitals and to obtain prior approval from their primary care physicians for other primary care.

The HCFA should address the problems identified by vulnerable beneficiaries in Medicare risk HMOs and we suggest these options: (1) In developing the health status capitation risk adjusters required by the Balanced Budget Act of 1997, HCFA should take into account the following considerations: (a) servicing access problems encountered by vulnerable populations in HMOs should continue to be monitored and (b) contractural requirements could be used by HCFA to encourage or require plans to designate specialists as primary physicians in appropriate cases or to provide standing referrals for ongoing specialty care needs. (2) The HCFA could also use contractural requirements to assure that referral and utilization criteria are available on request to providers and to beneficiaries for use in accessing care and appealing any denials of service.

Status

Management Response

The HCFA is currently revising its monitoring strategy and will be taking OIG's recommendations into consideration as it develops a new monitoring strategy. Recommendation #2 may be addressed through the Part C regulation at 42 CFR 422.111(c)(3) which requires Medicare+Choice Organizations to disclose the procedures used by the organization to control utilization of services and expenditures.

Extend PRO Review of Physician Office Surgery

Report Number: OEI-07-91-00680 Final Report: 6/93

Finding

One-fifth of medical records reviewed did not document reasonable quality of care for surgeries in a physician's office.

Thirteen percent of the medical records did not document an indication for surgery.

The physician's office was not an appropriate setting for a small number of surgeries.

In 16 percent of our sample cases, procedure codes did not match the surgeries performed.

Current Law/Policy

Section 1154(a)(4)(A) of the Social Security Act required that "Each peer review organization (PRO) shall provide thata reasonable allocation of such [quality review] activities is made among the different cases and settings" except that PRO review in physician offices could not begin before January 1, 1989. The PROs' reviews still do not extend to services performed in physician offices.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

The PROs should extend their review to surgery performed in physicians' offices.

Status

Management Response

Under the PRO 6th Scope of Work, PROs will examine several kinds of services in the office setting (immunizations, breast cancer screening, and diabetic care). In addition, a regulation now approaching final publication will complete the regulatory basis for obtaining physician office records. Also, HCFA has issued policy guidance and manual instructions to explicitly state that PROs have the responsibility to review all care in physicians' offices when a beneficiary complains.

Collect Overpayments for Routine Prenatal and Postpartum Care for Undocumented Aliens

Report Number: OEI-07-96-00310 Final Report: 5/98

Finding

Six States have claimed Federal funds for routine prenatal and postpartum care for undocumented alien women. Three still do. Survey respondents in 31 States and territories indicated they were not aware of HCFA's guideline on this subject. Two HCFA regional offices did not send guidance to States. A Federal court has ordered continuation of benefits in New York.

Current Law/Policy

The Omnibus Budget Reconciliation Act of 1986 amended the Social Security Act to limit Federal payment for emergency medical services under the Medicaid program to undocumented aliens except in certain cases. The amendment explains that an emergency medical condition occurs when the patient's health would be in serious jeopardy caused by serious impairment to bodily functions, or serious dysfunction of any bodily organ or part without immediate medical attention. This includes labor and delivery but does not include routine prenatal and postpartum care.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

In an earlier inspection, we found two States were improperly claiming Federal funds for routine postpartum medical care for undocumented alien women. Since misinterpretation or misunderstanding of the law on this matter continues to exist in some States, we recommend that HCFA: identify and recover Federal funds that Minnesota, Nebraska, Oklahoma, Vermont, and West Virginia inappropriately claimed; assure States and territories are aware of and implement policy and provisions applicable to claiming Federal funds; and continue to monitor and support the Department of Justice's efforts to resolve the legal issues involving New York.

Status

Management Response

The HCFA concurs with the recommendations. The HCFA will ask the regional offices to follow up with the States cited to recover the potential overpayments, and remind States and territories of the policy provisions. The HCFA will continue to actively support the Department of Justice in resolving the issues raised in the lawsuit.

Provide Additional Guidance to Drug Manufacturers to Better Implement the Medicaid Drug Rebate Program

Report Number: OAS-06-91-00092 Final Report: 11/92

Finding

Although manufacturers' best price determinations were acceptable, calculations of average manufacturer price (AMP) were inconsistent. The variations occurred because HCFA had not provided sufficiently detailed instructions to manufacturers on acceptable methods for calculating AMP. The method used impacts the AMPs, the resulting rebates, and the accuracy, reliability and consistency of the pricing information provided to HCFA.

Current Law/Policy

Section 1927 of the Social Security Act requires drug manufacturers to enter into and comply with rebate agreements with the Secretary in order for States to receive Federal financial participation for a manufacturer's covered outpatient prescription drugs. In accordance with Section 1927, manufacturers are required to report their AMP to HCFA for each covered outpatient drug for a base period. On a quarterly basis, the manufacturer is then required to report the AMP and the best price for each covered outpatient drug.

Recommendation	Legislative	A dministrative	Material Weakness

The HCFA should survey manufacturers to identify the various calculation methods used to determine AMP. The HCFA should also develop a more specific policy for calculating AMP which would protect the interests of the Government and which would be equitable to the manufacturers.

Status

Management Response

The HCFA did not concur, stating that the drug rebate law and the rebate agreements already established a methodology for computing AMP. We disagree. The rebate law and agreement defined AMP but did not provide specific written methodology for computing AMP.

Orange Book 1998-99 Prescription Drugs Page 51 of 93

Implement Proper Accountability Over Billing and Collection of Medicaid Drug Rebates

Report Number: OAS-06-92-00029 Final Report: 5/93

Finding

None of the eight States reviewed maintained general ledger control accounts for Medicaid drug rebates, and only four States maintained even informal receivable listings for each manufacturer. Additionally, it did not appear that the States reviewed were generally using their best efforts to collect the billings or resolve disputes with manufacturers. Also, there was virtually no system of internal controls in place in these States for drug rebate program funds.

Current Law/Policy

Federal regulations at 45 CFR, part 74, require that States meet certain standards for grant financial management systems which provide for (1) accurate, current, and complete disclosure of the financial results of programs; (2) accounting records which identify adequately the source and application of program funds; and (3) effective internal controls and accountability over all grant cash, property, and other assets so that these assets are safeguarded.

Recommendation Legislative Administrative Material Wea
--

The HCFA should ensure that States implement accounting and internal control systems in accordance with applicable Federal regulations for the Medicaid drug rebate program. Such systems must provide for accurate, current, and complete disclosure of drug rebate transactions and provide HCFA with the financial information it needs to effectively monitor and manage the Medicaid drug rebate program.

Status

Management Response

The HCFA concurred with the recommendation. States will now be required to maintain detailed supporting records of all rebate amounts invoiced to drug companies using a formal accounts receivable system. The HCFA issued interim regulations in FY 1996.

Orange Book 1998-99 Prescription Drugs Page 52 of 93

Overview

The activities conducted and supported by Public Health programs represent this country's primary defense against acute and chronic diseases and disabilities. The Public Health program area provides the foundation for the Nation's efforts in promoting and enhancing the continued good health of the

American people. It encompasses: National Institutes of Health (NIH), to advance our knowledge through research; Food and Drug Administration (FDA), to assure the safety and efficacy of marketed food, drugs, cosmetics and medical devices; Centers for Disease Control and Prevention (CDC), to combat preventable diseases and protect the public health; Health Resources and Services Administration (HRSA), to support through financial assistance the development of our future generation of health care providers; Indian Health Service (IHS), to improve the health status of Native Americans; Agency for Toxic Substances and Disease Registry (ATSDR), to address issues related to Superfund toxic waste sites; the Agency for Health Care Policy and Research (AHCPR), to enhance the quality and appropriateness of health care services and access to services through scientific research and the promotion of improvements in clinical practice, and in the organization, financing and delivery of services; and the Substance Abuse



Introduction

and Mental Health Services Administration (SAMHSA), to provide leadership in mental health and substance abuse treatment and prevention.

Highlights of OIG Activities

The Office of Inspector General (OIG) continues to increase oversight of Public Health program activities. The OIG concentrates on such issues as biomedical research, substance abuse, acquired immune deficiency syndrome and medical effectiveness. In addition, OIG conducts audits of colleges and universities which are awarded contract and grant funding by the Department of Health and Human Services (HHS). The OIG will continue to examine the systems in place to ensure that research funds are monitored properly. Other areas of review will include grants management in general, information resource management, food and drug programs, community health programs, and IHS financial management.

Orange Book 1998-99 Page 54 of 93

Comply with Federal Printing Program Requirements

Report Number: OAS-15-98-80001 Final Report: 3/99

Finding

The NIH did not always comply with the Federal Depository Library (FDL) Program or the Government Printing Office's (GPO) cataloging and indexing requirements. In addition, some NIH components printed items through commercial vendors that should have gone through GPO.

Current Law/Policy

The Public Health Service Act found at 42 U.S.C., Section 284(c)(4) allows each Director of a national research institute to publish or arrange for the publication of information pertaining to the institute without regard to the requirement that all printing be done at GPO. Also, 44 U.S.C., Section 1902-1903 requires Government components that obtain publications from sources other than GPO to furnish GPO a list of such publications issued during the previous month, and Section 1710 requires the head of each Government component to deliver a copy of every document issued or published to GPO for cataloging and indexing.

Recommendation Legislative	A dministrative	Material Weakness
----------------------------	------------------------	-------------------

The NIH should ensure that (1) all affected institutes are aware of their responsibilities regarding the FDL program and the cataloging and indexing program; (2) the responsible institutes provide FDL copies to GPO for sampled items GPO has identified as of current public interest; (3) the responsible institutes provide one cataloging and indexing copy to GPO for sampled items not previously sent to GPO; (4) it begins monthly reporting to GPO on all commercially printed publications; (5) Printing and Reproduction Branch officials adhere to requirements when providing printing services to NIH components that do not have independent printing authority; and (6) NIH components with no independent printing authority are aware of the requirement to print through GPO.

Status

Management Response

In its July 1999 status report, NIH stated that all recommendations had been satisfied. However, we found that NIH's reported actions on recommendations 2 and 3 above did not address providing FDL and cataloging and indexing copies to GPO for items sampled in our review. We are inquiring about the status of these actions. The intent of our remaining recommendations has been met.

Orange Book 1998-99 Biomedical Research Page 55 of 93

Strengthen Institutional Review Boards

Report Number:	OEI-01-97-00190	Final Report:	6/98
	OEI-01-97-00191		6/98
	OEI-01-97-00192		6/98
	OEI-01-97-00193		6/98
	OEI-01-97-00194		10/98

Finding

We found that the effectiveness of the institutional review boards (IRBs) is in jeopardy. They face major changes in the research environment, they review too much too quickly and with too little expertise. They conduct minimal continuing review of approved research, they face conflicts that threaten their independence, they provide little training for investigators and board members and neither the IRBs nor the Department devotes much attention to evaluating IRB effectiveness.

Current Law/Policy

Two agencies with HHS share responsibility for IRB oversight: the Office for Protection from Research Risks (OPRR) and the Food and Drug Administration (FDA). The OPRR's main tool for oversight is the assurance document which must be on file for any institution that intends to conduct HHS-funded research. The FDA's main mechanism for IRB oversight is the inspection process.

Recommendation	Legislative	✓ Administrative	Material Weakness

We directed our recommendations jointly to the NIH OPRR and the FDA. We recommended that OPRR and FDA (1) recast Federal IRB requirements so that they grant IRBs greater flexibility and hold them more accountable; (2) strengthen continuing protections for human subjects participating in research; (3) enact Federal requirements that help ensure that investigators and IRB members are adequately educated about and sensitized to human-subject protection; (4) help insulate IRBs from conflicts that can compromise their mission in protecting human subjects; (5) recognize the seriousness of the workload pressures that many IRBs face and take actions that aim to moderate them; and (5) reengineer the Federal oversight process.

Status

Management Response

While neither FDA nor NIH have implemented the recommendations, the FDA and NIH have taken some intermediate actions. The FDA has convened an agency wide task force to address our recommendations. The task force has prepared a draft report that has not been released to date. The FDA has also hosted a national conference on these issues. The FDA, NIH, and major organizations representing IRB interests participated in a May 1999 meeting to address developing an accreditation process for IRBs.

Orange Book 1998-99 Biomedical Research Page 56 of 93

Improve the Process by Which Blood Establishments Notify FDA of Errors and Accidents Affecting Blood

Report Number: OAS-03-93-00352 Final Report: 5/95

Finding

Error and accident reports were not submitted timely by blood establishments, and there was no assurance that unlicensed establishments were voluntarily submitting the reports.

Current Law/Policy

The Public Health Service Act (Title 42, U.S.C. 262) and the Federal Food, Drug and Cosmetic Act (Title 21, U.S.C. 331) place the responsibility for the oversight of blood establishments with FDA.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

The FDA should (1) expedite the development and issuance of revisions to Federal regulations on error and accident reporting (21 CFR 600.14(a)) to be more specific concerning the time frame in which reports are required to be submitted; (2) expedite the development and issuance of regulations to require unlicensed blood establishments to submit error and accident reports; and (3) expand the Center for Biologics Evaluation and Research's (CBER) use of information in its current error and accident data base to identify blood establishments that regularly fail to submit error and accident reports in a timely manner and provide additional trend analysis reports to FDA field offices and blood establishments.

Status

Management Response

The CBER is (1) pursuing proposed revisions to the Title 21, CFR 600.14(a), Reporting of Errors, (2) taking the necessary regulatory action to require unlicensed blood establishments to submit error and accident reports; and (3) using its existing data base and information management systems to identify establishments that do not make timely reports of errors and accidents.

Orange Book 1998-99 Food and Drug Safety Page 57 of 93

Improve FDA's Inspection Process for Plasma Fractionators

Report Number: OAS-03-97-00350 Final Report: 6/97

Finding

As part of this congressional request, we found that improvements were needed in FDA's plasma fractionator inspection process. Compared with plasma fractionator inspections by the Center for Biologics Research and Evaluation (CBER), the inspections by the Office of Regulatory Affairs (ORA) resulted in more reported observations of reportable conditions and more enforcement actions.

Current Law/Policy

Blood and blood products are licensed and inspected under Section 351 of the Public Health Service Act (42 U.S.C. 262).

The FDA should (1) implement as much as possible of ORA's Biological Advisory Committee proposal to improve the inspection process, (2) ensure that CBER has a viable plan for transferring inspection responsibilities to ORA, (3) adhere to time frames established for preparing inspection reports and issuing warning letters, (4) instruct employees on the importance of completing the classification of inspections, and (5) finalize and implement changes in the inspection guide for source plasma establishments.

Status

Management Response

The FDA is implementing a plan entitled "Team Biologics--A Plan for Reinventing FDA's Ability to Optimize Compliance of Regulated Biologics Industries" to ensure a smooth transfer of inspection responsibility to ORA. According to FDA, this plan incorporates the ORA Biological Advisory Committee's proposals to the extent possible. The FDA has instructed its field offices to adhere to time frames for preparing inspection reports, issuing warning letters, and classifying inspections and has finalized its inspection guides for plasma establishments.

Orange Book 1998-99 Food and Drug Safety Page 58 of 93

Improve the Reporting Process for Investigational New Drugs Regulated by FDA's Center for Biologics Evaluation and Research

Report Number: OAS-15-96-50001 Final Report: 7/98

Finding

The process for obtaining annual reports on investigational new drugs (INDs) does not ensure that the reports are consistently received on time or even at all. The Center's ability to oversee active INDs is diminished when the reports are not received because it may not obtain critical information, such as the number of study subjects who died, dropped out of the study, or suffered adverse experiences.

Current Law/Policy

The CFR, Title 21, Part 312.33 requires sponsors to submit to FDA a report on the progress of the IND investigation within 60 days of the anniversary date that the IND went into effect and annually therefore.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

To improve its process for collecting overdue reports, FDA should (1) underscore the importance of annual reports by establishing goals for improving the report collection process and reducing the number of reports outstanding; (2) take a more proactive role in obtaining the annual reports by sending informational letters to sponsors to remind them of the requirements for annual reports or by posting reminder notices to the Center's website; (3) further automate the process for collecting outstanding annual reports, including making improvements to the Biologics IND Management System (BIMS), which is used to track INDs; (4) improve staff training and written instructions for collecting IND annual reports; and (5) redesign the standardized application and amendment cover to facilitate recognition of administrative changes crucial to tracking an IND and ensure they are entered into BIMS.

Status

Management Response

In response to a draft of this report, the FDA generally concurred with these recommendations.

Orange Book 1998-99 Food and Drug Safety Page 59 of 93

Process Citizen Petitions in a More Timely Manner

Report Number: OAS-15-97-50002 Final Report: 7/98

Finding

The FDA does not have an effective process for handling citizen petitions in a timely manner, as evidenced by a backlog of approximately 250 petitions that have not been fully answered, some dating to the 1970's and early 1980's.

Current Law/Policy

The FDA regulations in 21 CFR, Part 10, Section 10.30 permit any person to submit a citizen petition requesting the Commissioner of Food and Drugs to (1) issue, amend, or revoke a regulation or order or (2) take or refrain from taking any other form of administrative action. The Commissioner is required, within 180 days of receipt of the petition, to approve the petition, deny the petition, or provide a tentative response indicating why FDA has not been able to reach a decision on the petition.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

The FDA should (1) eliminate the backlog by corresponding with petitioners whose requests are of long standing to determine if they still want FDA to take action on their petitions and by establishing time-phased target dates for handling first the oldest petitions with the most serious public health implications and (2) prevent a new backlog by developing agencywide optimal policies and procedures for responding to citizen petitions, by establishing management and oversight responsibility for the citizen petition process in the Office of the Commissioner, and by including time spent working on citizen petitions as a category of the agency's time reporting system.

Status

Management Response

The FDA remains committed to implementing these recommendations and is working on a proposed rule to revise citizen petition regulations.

Orange Book 1998-99 Food and Drug Safety Page 60 of 93

3/98

Evaluate Internal Controls Over FDA Purchase Card Activities

Final Report:

The FDA has not formally assessed the effectiveness of its compensating controls for lack of separation of duties in the use of its purchase cards. The FDA allowed cardholders to order, receive, and then sign for the receipt of goods and services purchased with the cards.

Current Law/Policy

The GAO guidance on internal controls, Separation of Duties; Appendix II, Title 2, states that to reduce the risks of error, waste, or wrongful acts, or to reduce the risk of their nondetection, key duties are to be separated between different individuals.

Recommendation

Legislative

Administrative

Material Weakness

The FDA should fully evaluate the adequacy of controls over the purchase card program which the agency believes compensate for the lack of separation of duties.

Status

Management Response

Report Number: OAS-15-97-80002

The FDA established an evaluation team which determined that the compensating controls in place were sufficient, purchases were well documented, and communication between cardholders and approving officials was good. However, the team made some suggestions in the areas of training and communication.

Orange Book 1998-99 Food and Drug Safety Page 61 of 93

Enforce State Pharmacy Boards' Oversight of Patient Counseling Laws

Report Number: OEI-01-97-00040 Final Report: 8/97

Finding

(1) State pharmacy boards have played an active role in explaining and urging pharmacist compliance with State patient counseling laws. (2) However, the boards' enforcement of the counseling laws has been minimal. (3) The boards identified major obstacles to the successful implementation of patient counseling laws.

Current Law/Policy

In 1990, Congress required pharmacists to offer counseling to Medicaid beneficiaries who present prescriptions and that States establish counseling standards. Nearly all States responded by passing laws that extend patient counseling to all patients, not just Medicaid beneficiaries. State pharmacy boards oversee compliance with these laws.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

(1) The FDA should collaborate with State pharmacy boards to collect survey data on the usefulness of written information offered to individuals receiving new prescriptions. (2) The HCFA should facilitate State efforts to enforce the Medicaid patient counseling mandate. (3) The HCFA should develop and assess State progress toward a patient counseling performance objective. (4) The HCFA should develop guidelines on State oversight of the Federal patient counseling mandate.

Status

Management Response

The FDA agreed with our recommendation to collaborate with State pharmacy boards to collect data on the usefulness of written information to patients. The FDA has let a contract to the National Associate Board of Pharmacy to begin collecting data about usefulness of written information to patients. The FDA intends to use this information to measure progress being made by pharmacists following the criteria established in the Prescription Information Action Plan.

The HCFA concurred with our recommendation to facilitate State efforts to enforce the Medicaid patient counseling mandate. The HCFA will assist States by amending the Drug Utilization Review Annual Report instructions to collect specific information regarding the compliance, monitoring and effectiveness of these efforts. In addition, HCFA will gather best practices from the States and distribute this information to all pharmacy boards.

Orange Book 1998-99 Food and Drug Safety Page 62 of 93

Require Participation in the 340B Drug Pricing Program for All Eligible Entities

Report Number: OAS-01-98-01500 Final Report: 7/98

Finding

Although the 340B program provides access to drugs at discounted prices, covered entity participation in the program is voluntary. The HRSA Office of Drug Pricing's data base indicates that approximately 66 percent of eligible grantees do not participate in the program. Consequently, HRSA's eligible nonparticipating grantees may not be purchasing covered outpatient drugs at the best prices.

The HRSA drafted a Federal Register Notice to request public comments on a proposed grant award condition requiring participation in the 340B program. Such participation would be required for all eligible entities that receive grants listed in Section 340B(a)(4) of the Public Health Service Act and that purchase or reimburse for covered outpatient drugs. This action was taken in response to a recommendation in our earlier report, "State AIDS Drug Assistance Programs' Use of Drug Price Discounts" (A-01-97-01501).

Current Law/Policy

The Congress enacted Section 340B of the PHS Act to provide effective means of lowering drug prices for covered entities. Also, CFR, Title 42, Chapter 1, Part 50, Subpart E, stipulates that the Department's policy is to expend program funds for the acquisition of drugs in the most economical manner feasible.

ceonomical manner reastore.			
Recommendation	Legislative	✓ Administrative	Material Weakness
We recommended that HRSA constants and the second s	ontinue its effort to requi	re eligible entities to parti	icipate in the
Status			

Management Response

The HRSA concurred with the recommendation and, in October 1998, published a Federal Register Notice requesting comments on a proposed grant award condition that eligible grantees participate in the 340B program. The HRSA received comments from 27 organizations, all negative. Instead of issuing the notice, HRSA decided to issue guidance on the existing regulatory requirement to expend funds for the acquisition of drugs in the most economical manner feasible. It also decided to provide technical assistance and training on the 340B program, along with a policy statement indicating that it expects eligible grantees and Federally Qualified Health Center Look-Alikes that purchase or reimburse for drugs to participate in the 340B program unless doing so does not make good business sense.

Orange Book 1998-99 **Health Resources and Services** Page 63 of 93

Improve Management of the Office of Program Integrity and Ethics

Report Number: OEI-04-97-00060 Final Report: 11/98

Finding

We found that the mission, policies and procedures for the Office of Program Integrity and Ethics are not clear. In addition, organizational structure obscures visibility and prominence; and organizational placement fragments responsibility for personnel security. Also, staffing may be inadequate.

Current Law/Policy

The IHS Director asked the Office of Inspector General to evaluate, for effectiveness, the operation of its program integrity and ethics functions. The Office of Program Integrity and Ethics investigates complaints about IHS and tribal employees, performs ethics activities, and coordinates personnel suitability investigations.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

We recommend that the IHS should: (1) Finalize its policies and procedures manuals and distribute it to all offices as soon as possible. The manual should delineate the integrity and ethics responsibilities of all IHS components, and procedures for components to follow. (2) Evaluate the adequacy of staffing.

Status

Management Response

The IHS concurs with our recommendations. The IHS is in the process of finalizing its policies and procedures manual which will delineate the integrity and ethics responsibility of all IHS components. In addition, the Office of Program Integrity and Ethics currently maintains a listing of "Area Ethics Contacts," for all IHS area offices. This listing is utilized as the master contact points for all IHS ethics issues.

Orange Book 1998-99 Indian Health Page 64 of 93

Strengthen Policies and Procedures for Medical Personnel Credentialing and Privileging at IHS and HRSA

Report Number: OAS-15-94-00006 Final Report: 12/96

Finding

The Federal credentialing and privileging policies at facilities operated directly by IHS and NIH are adequate but need to be strengthened for nonfederally operated, community-based programs funded by IHS and HRSA. Those funded by IHS are generally not required to follow Federal policy, and HRSA-funded programs have not been provided sufficient instructions.

Current Law/Policy

The HHS agencies that employ health professionals are required to implement the Assistant Secretary for Health's "Public Health Service Policy and Procedures on Minimum Standards of Appointment, Credentials Review, and Clinical Privileging."

Recommendation	Legislative	Administrative	Material Weakness
	Legislative	/ Maininguative	Iviaterial vv cakitess

We recommended that (1) IHS advocate programs for quality and risk management, specifically those related to credentialing and privileging of medical personnel in self-determination tribal health care programs; (2) HRSA disseminate detailed information on the operation of a comprehensive credentialing and privileging program to community, migrant, homeless, and public housing health center grantees; (3) the IHS and HRSA modify their employment and credentialing policies and practices to require, as a routine procedure, a search of the OIG Medicare and Medicaid exclusion list; and (4) the PHS Interagency Advisory Council on Quality Assurance and Risk Management revise its credentialing policy to require a search of the OIG Medicare and Medicaid exclusion list.

Status

Management Response

The IHS is continuing to advocate the use of credentialing and privileging procedures in tribally operated facilities. The HRSA distributed IHS' Credentialing Handbook to its grantees and is searching the OIG sanctions report before hiring providers. Also, in FY 1997, HRSA began adding Medicare/Medicaid exclusion information to its National Practitioner Data Bank. By augmenting the Data Bank, which already is required to be queried by the PHS Interagency Council credentialing policy (as well as many private health care entities), HRSA is greatly increasing exposure and access to the Medicare/Medicaid exclusion information.

Orange Book 1998-99 PHS Administration Page 65 of 93

Establish an FDA Performance Measurement System in Compliance with the Prompt Payment Act

Report Number: OAS-15-96-40002 Final Report: 5/97 **Finding** The FDA has not established a systematic, agencywide performance measurement system to assess its payment system. **Current Law/Policy** The OMB Circular A-125 requires agencies to establish a systematic performance measurement system throughout each agency to estimate payment performance, provide managers information on problems, and assist in targeting corrective action. Recommendation Administrative Legislative Material Weakness The FDA should assess its payment process at headquarters to include (1) assessments of transactions processed using standard payment procedures; (2) comparisons and analyses of payment system data with original purchase orders, invoices, and receiving reports for selected transactions; and (3) adjustments made when compiling data reported by field offices. **Status**

Management Response

The FDA is working to establish a performance measurement system for assessing the performance and reporting of headquarters' payments to vendors, and a policy requiring implementation of the system is under development. Individuals independent of the FDA Accounting Operations Branch will make the periodic assessments, which will be schduled depending on the availability of resources.

Orange Book 1998-99 PHS Administration Page 66 of 93

Develop Plan to Address Youth Use of Cigars

Report Number: OEI-06-98-00020 Final Report: 2/99

Finding

Cigars have not faced the same degree of Federal regulation and oversight as other tobacco products, such as cigarettes and spit tobacco. State enforcement of laws and regulations prohibiting the sale to, and use of cigars by, minors is currently severely limited. Lack of resources and a low enforcement priority are seen as the most significant barriers to effective control of cigar use by minors.

Current Law/Policy

The Synar Amendment to the Public Health Service Act requires States to have in place a law that prohibits the sale or distribution of any tobacco product to individuals under the age of 18 (minors) through any sales or distribution outlet and to reduce the rate of sale of cigarettes to minors according to a plan agreed to with SAMHSA. States face the loss of significant amounts of the Substance Abuse and Treatment block grant if they do not show progress in reducing the sales of cigarettes to minors on a yearly basis. Synar is not currently enforced for cigars.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

We recommend that the Department, under the leadership of the Assistant Secretary for Health, develop an action plan to address the public health risks posed by cigars, particularly access by youth. As a first step, we recommend an initiative to inform the public of the health risks through public education that is appropriate for cigars. As a second step, the Department should address the need for additional research on cigars.

Status

Management Response

We have not received an action plan from the Assistant Secretary for Health to date. However, the Surgeon General continues to take a public stance against cigar smoking and in favor of warning labels on cigars.

Orange Book 1998-99 PHS Administration Page 67 of 93

Expand Dissemination of Treatment Improvement Protocols

Report Number: OEI-07-96-00130 Final Report: 3/98

Finding

Thirty-two percent of SAMHSA funded grantees reported that they were aware of at least one of five Treatment Improvement Protocols (TIPS) referenced in our survey. Eighty-six percent of FDA narcotics/methadone treatment providers responded that they were aware of at least one of the five TIPS while thirty-two percent of community heath centers reported they were aware of at least one of the five TIPS.

Current Law/Policy

The TIPS are consensus-based "best practices" guidelines developed for SAMHSA for use in the treatment of individuals with alcohol or drug problems. Since 1993, 23 TIPS have been developed and issued at a cost of about \$300,000 each.

Recommendation	Legislative	Administrative	Material Weakness
	Legislative	/ Maininguative	Widterfai W Carriess

The SAMHSA should: (1) take a more proactive approach to advertising the availability of all past and future TIPs, and (2) consider expanding their "target audience."

Status

Management Response

In a May 17, 1998 corrective action plan SAMHSA advised the OIG, as follows: (1) The agency instituted a national press conference to launch the release of each new and revised TIP. (2) Beginning with the TIP 24, "A Guide to Substance Abuse Care for Primary Care Clinicians", the agency is "redoubling" its efforts to work with the trade press to develop targeted articles that provide in-depth review of the individual TIP. (3) The agency is conducting a short-term series of focus groups to develop better dissemination strategies. (4) The agency will disseminate each TIP to professionals allied with the substance abuse and related interest groups not previously targeted.

Orange Book 1998-99 PHS Administration Page 68 of 93

Develop Performance Measures for Detoxification Services for Medicaid Beneficiaries

Report Number: OEI-07-97-00270 Final Report: 11/98

Finding

We found that 15 States report having a formal process for providing transition from substance abuse detoxification to treatment; 32 have informal processes. We also found that States tailor substance abuse programs to complement their own service delivery systems, have limited data on detoxification and treatment activity outcomes; one-third of States conduct performance monitoring of substance abuse programs and; States seldom use outpatient settings for detoxification services.

Current Law/Policy

Detoxification and substance abuse treatment are funded federally by the Health Care Financing Administration (HCFA) and the Substance Abuse and Mental Health Administration (SAMHSA.) Annually, the SAMHSA spends over \$1.5 billion on substance abuse prevention and treatment services. In addition, HCFA covers substance abuse detoxification and treatment in most State Medicaid programs.

Recommendation	Legislative	Administrative	Material Weakness
The SAMHSA and HCFA should v	work with States to de	velop appropriate perform	nance measures.

Status

Management Response

As of January 1999, SAMHSA is working with the National Association of State Alcohol and Drug Abuse Directors to identify core outcome measures for treatment. The SAMHSA is responsible for conducting analyses of Medicaid managed care contracts for mental health and substance abuse treatment. As a result of the findings of these analyses, several technical assistance documents on contracting with managed care have been developed for States. Working in collaboration with HCFA, these documents are being disseminated and technical assistance is being provided to States and Medicaid directors on contracting language.

Overview

The Department's Children and Families program provides Federal direction and funding for State, local, and private organizations as well as for State-administered programs designed to promote

stability, economic security, responsibility and self-support for the Nation's families. It also oversees a variety of programs that provide social services to the Nation's children, youth, and families, persons with developmental disabilities and Native Americans.

Major types of family support payments to States include: Temporary Assistance for Needy Families (TANF), a cooperative program among Federal, State and local governments that was in effect in 1996; and the Child Support Enforcement (CSE) program, which provides grants to States to enforce obligations of absent parents and establishing and enforcing child support orders. The Head Start program provides comprehensive health, educational, nutritional, social and other services to preschool children and their families who are economically disadvantaged. The Foster Care and Adoption



Introduction

Assistance programs provide grants to States to assist with the cost of foster care and special needs adoptions, maintenance, administrative costs, and training for staff. Other programs include Community Services, and the State Legalization Impact Assistance Grants program.

Highlights of OIG Activities

The Office of Inspector General (OIG) continues to focus on oversight of Children and Families programs and activities, including reviews of the effectiveness of children and families social services and assistance programs. Particular emphasis is placed on welfare reform initiatives. We identify opportunities to improve the delivery of program services such as: collecting and distributing child support payments, improving oversight of Federal cash assistance programs and ensuring the Head Start program objectives are accomplished.

Orange Book 1998-99 Page 71 of 93

Consider Options for Assisting States in Effectively Managing the Federal Foster Care Program

Report Number: OAS-12-93-00022 Final Report: 8/94

Finding

This report analyzed findings in our audit reports issued over the last 3 fiscal years relating to the Federal Foster Care program. We noted that States were often unsuccessful in implementing the many requirements imposed by the Adoption Assistance and Child Welfare Act of 1980, P.L. 96-272. Specifically, they continue to have problems in complying with requirements for licensing, Aid to Families with Dependent Children eligibility, and the more complex requirements relating to voluntary placements and judicial determinations.

Current Law/Policy

The statutory requirements for Federal Title IV-E funding have continued to be difficult for States to meet. While the initial intent of these requirements was to help ensure the proper care and treatment of children, those same requirements now appear to be viewed by some Members of Congress, State officials, and child welfare advocates as overburdening the process, rather than assisting States in providing quality services in a cost-effective manner. Concerns have been raised about whether the Federal Foster Care program's focus should be on the quality of care and the provisions of services rather than on whether all requirements are met.

Recommendation	✓ Legislative	A dministrative	Material Weakness
----------------	----------------------	------------------------	-------------------

We provided options for ACF to consider in its efforts to improve its partnership with State and local governments. The options include streamlining the process, determining whether legislative change is needed to allow "substantial compliance" with eligibility requirements, and determining whether the requirements concerning the content of judicial determinations could be changed to a State plan compliance issue rather than remain as an eligibility issue.

Status

Management Response

The ACF concurred with the issues raised in our report and is piloting redesigned Titles IV-B and IV-E child welfare reviews. A Notice of Proposed Rulemaking was published in September 1998, and the final rule is in clearance. In addition, the child welfare waiver demonstrations are allowing several States to test alternative approaches to the Title IV-E requirements.

Orange Book 1998-99 ACF Administration Page 72 of 93

Review Availability of Health Insurance for Title IV-D Children

Report Number: OAS-01-97-02506 Final Report: 6/98

Finding

Taxpayers, rather than noncustodial parents (NCPs), provided medical support to nearly 14,000 Title IV-D children through the Medicaid program in Connecticut between April 1996 and March 1997. Although required by court order to provide health coverage to their children, these NCPs were unable to meet their obligation because either their employers did not offer health insurance or available health insurance was not reasonably priced. Using premium information from the State's current Medicaid managed care program, we believe Connecticut could save an estimated \$11.4 million (Federal and State combined) in annual Medicaid costs if it required NCPs to offset Medicaid premiums paid by the State on behalf of their children.

Current Law/Policy

The Child Support Enforcement program is authorized by Title IV-D of the Social Security Act.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

We recommended that Connecticut either (1) implement policies and procedures to require NCPs to pay all or part of the Medicaid premiums for their dependent children or (2) establish a statewide health insurance plan that provides reasonably priced comprehensive health coverage for children and requires NCPs to contribute toward a premium payment. We also suggested that ACF make our report available to other States for their consideration.

Status

Management Response

While beginning to develop a means of distributing our report to all States, ACF was required to establish, on behalf of HHS and with the Department of Labor, the congressionally mandated Medical Child Support Work Group. The group had the charge of developing a more expansive medical insurance strategy based partly on recommendations from a variety of sources, including the OIG. Pending the group's report to the Secretaries of HHS and Labor, ACF deferred distributing the OIG report.

Improve Child Support Enforcement Annual Report to Congress

Report Number: OEI-02-98-00070 Final Report: 10/98

Finding

We found that, overall, users are satisfied with and rely on the Office of Child Support Enforcement's Annual Report to Congress. They view it as a valuable and unique sources of child support program information. Users cite the report's lack of a clearly defined story line, program performance data, timelines, and data integrity as the report's main weaknesses.

Current Law/Policy

The Child Support Enforcement (CSE) program was established in 1975 under Title IV-D of the Social Security Act. It is administered at the State level and overseen federally by the Office of Child Support Enforcement (OCSE). In establishing the CSE program, Congress requires OCSE to submit an annual report to them no later than 3 months after the end of each fiscal year. While the legislation mandates the reporting of certain data, it does not define many of the data elements.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

(1) We recommend that ACF focus primarily on performance in the Report to Congress. Specifically, the Report should (a) highlight program successes, strengths, and weaknesses; (b) emphasize performance data with demonstrates how well the program is meeting its goals, and; © adequately describe program accomplishment that, when used to compare different program strategies, may be valuable to Federal policy makers and State programs. (2) We recommend that ACF review the report's production and distribution processes and identify specific actions to improve the report's timeliness.

Status

Management Response

The ACF concurred with our recommendations. According to ACF, beginning in Fiscal Year 1999, the annual report will reflect the Personal Responsibility and Work Opportunity Act of 1996 changes in the way data is gathered and reported. The ACF also anticipates that fundamental changes in the Child Support Enforcement program such as performance-based financial incentives for States, that require new forms and standards definitions, will change the way data is presented in the annual report. The ACF is working to streamline production and distribution of the annual report and plan to publish a preliminary data report for States and individuals.

Develop Effective Practices for Handling Facility Purchases by Head Start Program Grantees

Report Number: OAS-09-94-00085 Final Report: 6/96
Finding
We identified the following two areas of concern: (1) review and approval of purchase requests; and (2) accounting for facility purchases.
Current Law/Policy
Section 644(f) of the Head Start Improvement Act of 1992, Title 45 CFR, Part 74, sets forth requirements.
Recommendation Legislative Administrative Material Weaknes
We recommended that ACF (1) continue efforts to develop expertise for providing technical assistance to grantees acquiring or planning to acquire facilities; (2) require that property inspection reports submitted by grantees include the results of tests for environmental hazards; (3) require grantees to disclose any restrictions on the use of the facilities imposed by organizations providing supplemental funding; (4) ensure that all necessary documentation, such as property appraisals and inspection reports, is submitted prior to making grant awards; (5) ensure that purchase requests submitted by grantees describe all renovations that need to be made to the property and that grantees obtain professional help, if necessary, in determining the need for and estimated costs of renovations; (6) require grantees considering loans with balloon payments to disclose these plans, and explain how the balloon payment obligation will be met; (7) require grantees to consider coordinating the acquisition of Head Start facilities with the facility needs of programs funded by the Administration on Aging, such as senior citizen programs; (8) continue efforts to develop and implement a system to account for Head Start funds used for each facility purchased; and (9) provide guidelines to calculate the Federal interest in properties that are acquired with the assistance of funds from other programs and when a portion of the facility is used for other purposes.
Status

Management Response

In February 1999, ACF issued final regulations on facility purchases (codified at 45 CFR 1309) which implement recommendations 2 through 6 and 9 above. Recommendation 1 is addressed on the Head Start Bureau's Internet Homepage, and recommendation 8 has been addressed with the establishment of a facility tracking system. Only recommendation 7 concerning collaboration with AoA remains outstanding.

Improve Implementation of Interstate Compact for Placement of Children

Report Number:	OEI-02-95-00044	Final Report:	3/99	
Finding				
We found that St weaknesses are a	•	obligations under	the compact; however, s	ome
Current La	w/Policy			
	*		contract among the State	
Recommer	ndation	Legislative	Administrative	Material Weakness
support the effor	ts of the States and the	Association of A	vailable to States. The Administrators of the Inter's purpose, importance, a	state Compact
Status				
Management R	ocnonco			

The ACF will be funding six national resource centers and two child welfare training activities to support improvements.

Provide Guidance to Correct Vulnerabilities and Barriers to State's Child Care Certificate Systems

Report Number: OEI-05-97-00320 Final Report: 2/98

Finding

We found that in the child care certificate system, parental choice may be restricted by low provider payment rates and high co-payment rates. In addition, we found that State efforts may not be sufficient to ensure that health and safety standards are met.

Current Law/Policy

The Child Care and Development Block Grant Amendments of 1996 authorized and appropriated \$13.9 billion in mandatory and matching funding for Fiscal Years 1997-2002. The Child Care Development Block Grant (also called the Child Care Development Fund) requires States to give eligible families the option of (1) enrolling their children with an eligible provider that has a grant or contract or (2) receiving a child care certificate with which to purchase child care services.

Recommendation	Iaterial Weakness
----------------	-------------------

We recommended that ACF set forth the goals that States monitor all providers through professional inspections and know the backgrounds of all providers through background checks; help States establish background registries and a toll-free number to report problems and concerns; disseminate information about effective ways to enhance consumer education; and help States devise outcome measures of quality consumer education.

Status

Management Response

The ACF concurred with our recommendations. According to ACF's comments on our draft report, they are already working to address a number of our recommendations. The ACF has not yet developed a corrective action plan.

Provide Guidance to Tribal Child Care Programs

Report Number: OEI-05-98-00010 Final Report: 11/98

Finding

We found that the Child Care Development Fund (CCDF) grants provide Indian children greater access to child care. However, lack of State and Tribal coordination impacts costs, wastes resources, and opens up the potential for duplication payments. We also found that impediments exist in the coordination of Head Start and CCDF programs and that Tribal child care plans, payment systems and reporting are flawed.

Current Law/Policy

The Child Care Development Block Grant Act of 1996 (CCDBG), as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, now permits Tribal grantees to directly administer child care funds, in addition to operating CCDBG programs. The amended CCDBG Act also permits Tribal grantees to use funds for construction and renovation purposes. Indian children can access child care from their own Tribes, other Tribes or from a consortium. Tribal CCDF programs serve Indians living in self-defined service areas.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

We recommended that the ACF (1) encourage Tribes and States to develop reciprocal agreements, share systems and establish single points of enrollment; (2) compile and disseminate information about model Head Start/child care collaborative initiatives; and (3) provide model timesheets, model accounting practices and on-site assistance to Tribes.

Status

Management Response

The ACF concurred with our recommendations. In recognition of the specialized needs of the Tribal Child Care and Development Fund (CCDF) grantees, ACF awarded a contract, in January 1998, to establish a Tribal Child Care Technical Assistance Center (TriTAC) that will address many of our recommendations. In addition, the Child Care Bureau and the Head Start Bureau are continuing to provide direction and leadership to tribal child care programs on issues of collaboration, best practices and model approaches. The ACF agrees that the program data collected on the ACF-700 reporting form need to be examined and plan to convene a special "data" round table discussion at its National American Indian/Alaska Native Child Care Conference in March 1999.

Improve Oversight of Single Audits of Office of Community Services Grants

Report Number: OAS-12-92-00043 Final Report: 4/93 **Finding** We found problems with ACF's grant oversight in the areas of (1) ensuring that unexpended funds were returned, (2) accountability over receivables, and (3) monitoring and close-out of grants. **Current Law/Policy** The OMB Circular A-50 requires that management take corrective action on all audit findings. The Grants Administration Manual, Ch. 1-105-120, calls for monitoring by the operating division. Recommendation Legislative Administrative Material Weakness The ACF should (1) track implementation of recommendations made to grantees as a result of single audits and follow up with grantees to ensure actions taken were effective; (2) prepare appropriate OIG clearance documents; (3) send standardized demand letters that contain provisions for appeal and specific interest rates and provide 30-day follow-up until collections are complete; and (4) close out grants in a timely, accurate manner. **Status**

Management Response

The ACF agreed with our findings and recommendations and indicated it would take steps to implement the recommendations within the limitations of current staffing resources.

Orange Book 1998-99 Grants Management Page 79 of 93

Overview

Today, one in every six Americans, or 44 million people, are 60 years of age or older. While most older Americans are active members of their families and communities, others are at risk of losing their independence. These include four million Americans aged 85 and older, those living alone without a caregiver.

One Federal agency - the Administration on Aging (AoA) in the Department of Health and Human Services (HHS) - is dedicated exclusively to policy development, planning, and the delivery of supportive home and community-based services to our nation's diverse population of older Americans and their caregivers. The AoA also provides critical information and assistance and programs that protect the rights of vulnerable, at-risk older persons through the Older Americans Act of 1965.

Working in close partnership with its sister agencies in HHS and throughout the executive branch of Government, AoA leads a national aging network which includes AoA's central



Introduction

and regional offices, 57 State units on aging; 655 area agencies on aging, 223 tribal organizations, representing 300 tribes; and thousands of service providers, senior centers, caregivers, and volunteers.

Highlights of OIG Activities

The Office of Inspector General (OIG) continues to focus on oversight of older Americans programs and activities. Particular emphasis is on improving nutrition for the elderly, providing transportation, developing guidelines for ombudsman programs, and helping end the abuse, exploitation, and neglect of older people.

Orange Book 1998-99 Page 81 of 93

Strengthen the Long Term Care Ombudsman Program

Report Number: OEI-02-98-00351 Final Report: 3/99

Finding

We found that the Ombudsman program's overall capacity to monitor and promote nursing home care appears limited, primarily due to staffing constraints. Staffing constraints lead to limited regular nursing home visits by ombudsmen. State Ombudsman programs lack a common standard for responding to and resolving complaints. We also found that while the ombudsman data reporting system is still being improved, ombudsmen are not always sure how to report certain data.

Current Law/Policy

State Ombudsman programs have multiple functions that are mandated by law. They include: (1) identifying, investigating, and resolving complaints; (2) protecting the legal rights of patients; (3) advocating for systemic change; (4) providing information and consultation to residents and their families; and (5) publicizing issues of importance to residents.

Recommendation	Legislative	A dministrative	Material Weakness
----------------	-------------	------------------------	-------------------

We recommended that the Administration on Aging work with States to strengthen the Ombudsman program. In particular, we recommended that AoA: (1) develop guidelines for a minimum level of program visibility that include criteria for the frequency and length of regular visits, as well as a ratio of ombudsman to long-term-care beds; (2) further highlight and promote strategies for recruiting, training, and supervising more volunteers; (3) develop guidelines for complaint and resolution times; and (4) ensure that all State ombudsmen understand and use the definitions in the reporting system and train local ombudsmen and volunteers in standard utilization.

Status

Management Response

In comments to the draft report, AoA generally agreed with our recommendations. The AoA plans to work with States to develop guidelines and other forms of assistance on program visibility. The AoA provides training and technical assistance on how to recruit, train, place, and supervise volunteers annually to ombudsmen through the National Long-Term Care Ombudsman Resource Center. The AoA also indicated that it would encourage State ombudsmen to promote better understanding of the reporting system and to encourage training of local ombudsmen in the correct case and complaint documentation.

Improve Nutrition for the Elderly by Using U.S. Department of Agriculture Commodities

Report Number: OAS-01-93-02510 Final Report: 5/95

Finding

The 18 States we reviewed generally agree there are opportunities to provide more meals to older Americans, without increasing Federal expenditures, by using more U.S. Department of Agriculture (USDA) commodities.

Current Law/Policy

Under the Older Americans Act, AoA grants funds to State agencies on aging and tribal organizations for the Elderly Nutrition Program (ENP), which provides nutrition services to older Americans. The USDA also supports ENP through its Nutrition Programs for the Elderly (NPEs), which provides entitlements to States in commodities, cash, or a combination.

We recommended that AoA work closely with USDA to (1) expand the usage of commodities and (2) emphasize the importance of bonus commodities in States' decisions to either return to or expand their usage of commodities and work with the State distribution agencies to ensure an equitable distribution of bonus commodities between the NPEs and schools. Also, AoA should develop and communicate a uniform message to USDA on the concerns of dependability, quality, and packaging of commodities.

Status

Management Response

The AoA agreed with our findings and recommendations and agreed that promoting commodity usage may better expand nutrition services at a lower cost than other alternatives. The AoA believes developing innovative ways to expand nutrition services at a limited cost is essential. The AoA also believes the OIG's third recommendation can be addressed by using data obtained from the national evaluation of the ENP, convening with USDA a roundtable of community usage barriers, using input from the AoA National Nutrition Advisory Council, and recommending that the issue be addressed by the USDA National Advisory Council on Commodity Distribution.

Orange Book 1998-99 Nutrition and Services Page 83 of 93

Collocate Intergenerational Programs

Report Number: OAS-05-94-00009 Final Report: 1/95

Finding

Collocating the AoA senior centers with the ACF Head Start classroom encourages interactions and can be mutually beneficial to both seniors and children. Interviews with officials of intergenerational centers and recognized experts in the field corroborated our observations and conclusion that colocation of adults in senior centers with Head Start children would increase the quality and level of services offered to participants.

Current Law/Policy

The AoA, under Title IV of the Older Americans Act of 1965, has the authority for awarding grants and contracts to eligible organizations to establish demonstration projects that provide older individuals with intergenerational activities. Priority areas for funding are determined by the Assistant Secretary for Aging each year. Under Title V of the Economic Opportunity Act of 1964, the ACF Head Start program operates on the premise that children are best prepared for success in school when they and their parents participate in a comprehensive program that addresses their needs. For FYs 1990 through 1993, over \$1.5 billion in expansion funds was made available to increase enrollment and improve the quality of Head Start services.

Recommendation Legislative Administrative Material Weaking
Legislative V Administrative Material Wear

Because the scope of our review was limited, we were unable to make a recommendation that collocation be implemented nationwide. However, we recommended that AoA and ACF examine whether the demonstrated successes in collocating programs and facilities in the private and public sector can be more broadly applied on a voluntary basis. Where benefits for the young and old are recognized, AoA and ACF should (1) include provisions in their strategic plans to promote and encourage intergenerational programs and shared facilities on a voluntary basis, (2) pursue demonstrated opportunities and benefits available under the intergenerational concept by promoting more intergenerational activities and by encouraging more voluntarily collocated programs, and (3) strengthen and coordinate their volunteer programs to encourage elders to provide services to Head Start and other programs involving children.

Status

Management Response

The AoA and ACF headquarters and regional office staff generally supported the study and promotion of intergenerational activities, specifically the voluntary collocation of Head Start programs with senior centers.

Orange Book 1998-99 Nutrition and Services Page 84 of 93

Improve Safeguards for Long-Term-Care Residents

Report Number: OAS-12-97-00003 Final Report: 9/98

Finding

There is no assurance that nursing home staff who could place elderly residents at risk of abuse or neglect are systematically identified and excluded from employment. Not all States require criminal background checks of applicants or on-board staff, but those that do believe the checks have reduced the instances of abuse. Screening nurse aide registries can also be an effective tool in identifying known abusers, but in one State reviewed, the registry did not always record findings of abuse and convictions. Additionally, although use of the OIG exclusion list can make screens more effective, none of the nursing homes surveyed in six States was aware of this data base or its availability on the Internet.

Current Law/Policy

Under HCFA statute and regulations, residents of nursing homes and other long-term care facilities have the right to reside in a safe and secure environment, free from abuse and neglect. There is no Federal requirement to conduct criminal background checks of current or prospective employees of nursing facilities.

Recommendation	I egislative	Administrative	Material Weakness
Recommendation	Legislative	Administrative	Material Weakness

We recommended that (1) HCFA and AoA work collaboratively with the States to improve the safety of long-term care residents and to strengthen safeguards against the employment of abusive workers, (2) HCFA consider establishing Federal requirements and criteria for performing criminal checks, and (3) HCFA consider developing a national abuse registry or expanding the current State registries to include all workers in facilities receiving Federal reimbursement.

Status

Management Response

The HCFA and AoA verbally agreed with our recommendations.

Orange Book 1998-99 Nutrition and Services Page 85 of 93

Orange Book 1998-99 Financial Management Page 86 of 93

Overview

The Office of Inspector General's (OIG) departmental management and government wide oversight role includes reviews of payroll activities, accounting transactions, implementation of the Federal Managers' Financial Integrity Act and the Prompt Pay Act, financial management audits under the

Chief Financial Officers (CFO) Act, grants and contracts, the Department's Working Capital Fund, conflict resolution, and adherence to employee standards of conduct. The OIG also participates in interagency efforts through the President's Council on Integrity and Efficiency (PCIE) and the President's Council on Management Improvement to prevent losses to and abuses of Federal programs.



Introduction

In addition, OIG has oversight responsibility for audits conducted

of certain Government grantees by non-Federal auditors, principally public accounting firms and State audit organizations. The Office of Management and Budget (OMB) Circular A-133 assigns audit oversight responsibility to OIG for the majority of Federal funds awarded to major research schools, State and local government cost allocation plans, and separate indirect cost plans of State agencies and local governments. In addition, the OIG is responsible for auditing the Department's financial statements.

The general Department management includes overall direction for departmental activities and common services such as personnel, accounting and payroll to departmental operating divisions.

Highlights of OIG Activities

The OIG's work in departmental management and governmentwide oversight focuses principally on financial statement audits, financial management and managers' accountability for resources entrusted, standards of conduct and ethics, and governmentwide audit oversight, including recommending necessary revisions to OMB guidance. The OIG also reviews the adequacy of States' systems to control the growth of administrative/indirect costs claimed for Federal financial participation.

Orange Book 1998-99 Page 87 of 93

5/93

Update Cost Principles for Federally Sponsored Research Activities

Final Report:

The Department's hospital cost principles for federally sponsored research activities contained in CFR, Title 45, Part 74, Appendix E (known as OASC-3) are not up to date and do not always provide clear guidance for determining what types of costs should be allowed and how costs should be allocated.

Current Law/Policy

The OASC-3 was published over 25 years ago when the research environment and Federal funding rules were less complex. The OASC-3 does not always provide clear guidance for determining what types of costs should be allowed and how costs should be allocated.

Recommendation

Legislative

Administrative

Material Weakness

The Assistant Secretary for Management and Budget should modernize and strengthen the cost

principles applicable to hospitals by either (1) revising OASC-3, where applicable, with OMB Circular A-21 or (2) working with OMB to extend Circular A-21 coverage to all hospitals.

Status

Management Response

Report Number: OAS-01-92-01528

The Department's Division of Cost Allocation has formed a task force and is revising the OASC-3 hospital cost principles to match governmentwide cost principles for universities. These revisions are expected to take a long while to complete and implement.

Orange Book 1998-99 Financial Management Page 88 of 93

Incorporate Provisions for Implementing FASB 106 in Guidelines to Reimburse Educational Institutions and Nonprofit Organizations

Report Number: OAS-01-93-04000 Final Report: 6/93

Finding

The Financial Accounting Standards Board Statement Number 106 (FASB 106) affects postretirement benefit (PRB) costs claimed for reimbursement by schools and nonprofit organizations conducting federally sponsored research. The FASB 106 changed the treatment of PRB costs from the cash basis to the accrual basis of accounting.

Current Law/Policy

Currently, OMB Circulars A-21 and A-122, "Cost Principles for Educational Institutions" and "Cost Principles for Nonprofit Organizations," do not state whether the accrued portion of PRB expenses should be recognized as a reimbursable cost. Without guidance on whether accrued expenses should be charged, scarce Federal research funds may be used to reimburse unfunded PRB costs.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

The Assistant Secretary for Management and Budget (ASMB) should (1) work with OMB to revise applicable cost principles to address the impact of FASB 106 on PRB costs and (2) advise negotiators for the Division of Cost Allocation to pay special attention to PRB costs when reviewing fringe benefit rates for schools and nonprofit organizations.

Status

Management Response

The OMB has revised OMB Circular A-87 to limit PRB costs to the amount funded. While OMB agreed that similar provisions should be incorporated into Circulars A-21 and A-122, revisions made to these circulars in May and June 1998 did not address PRB costs. In the interim, ASMB has issued instructions to negotiators that PRB costs claimed under Circulars A-21 and A-122 should be treated in the same manner as the provisions of Circular A-87.

Orange Book 1998-99 Financial Management Page 89 of 93

Improve Recharge Centers' Financial Accounting Systems

Report Number: OAS-09-92-04020 Final Report: 1/94

Finding

Recharge centers of 11 of 12 universities reviewed did not maintain adequate accounting systems and records to allow for the development of billing rates based on actual costs or the identification of surplus or deficit fund balances. As a result, some recharge centers (1) accumulated surplus and deficit fund balances that were not adjusted in subsequent billing rates, (2) included duplicate or unallowable costs in billing rates, (3) included recharge center costs in the calculation of indirect cost rates, (4) used recharge center funds for unrelated purposes, and/or (5) billed some users at reduced rates. These practices overstated billing rates, resulting in overcharges of \$3.2 million to the Federal Government.

Current Law/Policy

The OMB Circular A-21, "Cost Principles for Educational Institutions," requires billing rates for recharge centers to be based on actual costs, designed to recover the aggregate cost of a good or service, and reviewed periodically.

Recommendation	Legislative	✓ Administrative	Material Weakness
----------------	-------------	-------------------------	-------------------

The Assistant Secretary for Management and Budget (ASMB) should require universities to (1) develop and implement policies and procedures for operating recharge centers consistent with OMB Circular A-21, (2) establish and maintain adequate accounting and recordkeeping procedures for recharge centers, and (3) and analyze and adjust billing rates to eliminate deficit and surplus funds.

In addition, the ASMB should work with OMB in revising Circular A-21 to ensure that criteria related to the financial operation of recharge centers are clear.

Status

Management Response

The ASMB asked OMB to clarify Circular A-21 regarding recharge centers, stating that recharge centers should be evaluated as part of an institution's A-133 audit. The ASMB role would then be to resolve reported A-133 deficiencies.

Orange Book 1998-99 Financial Management Page 90 of 93

Improve Financial Reporting Processes

Report Number: OAS-17-98-00001 Final Report: 4/98

OAS-17-98-00015 2/99

Finding

The Department and its operating divisions do not have fully integrated accounting systems capable of producing financial statements in a timely and efficient manner. Instead, HHS and many of its operating divisions use manual processes to summarize accounting data, make adjustments, and prepare financial statements. These manual processes increase the risk that financial statements may be materially misstated and contribute to delays in preparing statements.

Current Law/Policy

The Government Management Reform Act of 1994 requires that many Federal agencies, including HHS, prepare annual financial statements and establishes time frames for submitting audited statements. The OMB Bulletin 97-01 requires that financial statements be the culmination of a systematic accounting process, and OMB Bulletin 93-06, Audit Requirements for Federal Financial Statements, provides OIGs with guidance to audit and report on the statements.

ve Administrative	Material Weakness
	ve Administrative

We recommended that the Assistant Secretary for Management and Budget (ASMB) work toward establishing a more formal, structured process capable of producing complete and reliable financial statements in a timely manner. Recommended steps include, in part, assessing HHS staffing levels to ensure that sufficient resources are available to prepare annual statements without hampering day-to-day accounting operations and automating and standardizing manually intensive processes used to prepare financial statements.

Status

Management Response

The HHS is taking steps to ensure that departmentwide and operating division financial statements are prepared timely and are auditable.

Orange Book 1998-99 Financial Management Page 91 of 93

(Continued 2)

Report Number: OAS-17-98-00001 Final Report: 4/98

OAS-17-98-00015 2/99

Finding

At a number of operating divisions, there were significant delays in providing documentation supporting financial statement balances during the FY 1998 financial statement audits. We also noted numerous instances in which general ledger balances had not been periodically reconciled to supporting documentation. Reconciliation is an effective internal control for detecting and correcting duplicate postings, omitted entries, or incorrect transfer of data--all of which could result in material misstatements.

Current Law/Policy

The Government Management Reform Act of 1994 requires that many Federal agencies, including HHS, prepare annual financial statements. The OMB Bulletin 93-06, Audit Requirements for Federal Financial Statements, provides OIGs with guidance to audit and report on the statements.

Recommendation	Legislative	✓ Administrative	\checkmark	Material Weaknes
----------------	-------------	-------------------------	--------------	------------------

We recommended that ASMB oversee operating divisions' efforts to develop auditable documentation for financial statement amounts, ensure that accounting records are reconciled, and ensure that corrective actions continue on other accounting and control issues identified during audits of the HHS operating divisions.

Status

Management Response

The ASMB and operating divisions concurred and are taking steps to ensure that accounting records supporting financial statements are complete and accurate.

Orange Book 1998-99 Financial Management Page 92 of 93

Improve Accounting for Property, Plant, and Equipment at NIH and FDA

Report Number: OAS-17-98-00001 Final Report: 4/98

OAS-17-98-00015 2/99

Finding

Although NIH and FDA have improved their accounting for property, plant, and equipment (PPE), management must make a commitment to sustain this progress. The NIH has taken its first complete physical inventory of its PPE, totaling \$713 million, in 5 years. The results of the inventory identified \$27 million of capitalized assets that could not be located. Although this is an important first step, the effort will be lost unless NIH develops formal procedures to ensure proper accountability of assets and the monthly reconciliation of general ledger balances with personal property records.

During FY 1998, FDA completed a physical inventory of accountable personal property and reconciled its subsidiary ledger to the general ledger. Further policies and procedures were put in place for annual complete inventories and quarterly reconciliations of accounting records. However, we continued to find some differences between the property listing and property on hand. Although these differences did not have a material impact on FDA's financial statements, the cause of these types of discrepancies, if not correctly identified and promptly resolved, could undermine the progress FDA has made.

Current Law/Policy

The Federal Financial Management Improvement Act of 1996 requires Federal agencies to maintain acceptable accounting systems. Also, the Federal Managers' Financial Integrity Act of 1982 requires Federal entities to develop, maintain, and test the adequacy of their internal controls and financial management systems and to report on any material weaknesses and planned corrective actions.

planned corrective detions.			
Recommendation	Legislative	A dministrative	Material Weakness
Specific recommendations for correcommended that ASMB overse		1 0	ions. We also
Status			

Management Response

The ASMB and operating divisions concurred with the recommendations and are taking corrective actions.

Orange Book 1998-99 Financial Management Page 93 of 93

STATUTORY AND ADMINISTRATIVE RESPONSIBILITIES

Effective April 1989, statutory authority for the Office of Inspector General was transferred from Public Law 94-505 to 95-452, as amended. Other statutory and administrative reporting and enforcement responsibilities include:

AUDIT AND MANAGEMENT REVIEW RESPONSIBILITIES AND OFFICE OF MANAGEMENT AND BUDGET CIRCULARS

P.L. 96-304	Supplemental Appropriations and Rescissions Act of 1980
P.L. 96-510	Comprehensive Environmental Response, Compensation and Liability Act
P.L. 97-255	Federal Managers' Financial Integrity Act
P.L. 97-365	Debt Collection Act of 1982
P.L. 98-502	Single Audit Act of 1984
P.L. 99-499	Superfund Amendments and Reauthorization Act of 1986
P.L. 100-504	Inspector General Act Amendments of 1988
P.L. 101-121	Governmentwide Restrictions on Lobbying
P.L. 101-576	Chief Financial Officers Act of 1990
P.L. 102-486	Energy Policy Act of 1992
A-21	Cost Principles for Educational Institutions
A-25	User Charges
A-50	Audit Follow-up
A-70	Policies and Guidelines for Federal Credit Programs
A-73	Audit of Federal Operations and Programs
A-76	Performance of Commercial Activities
A-87	Cost Principles for State, Local and Indian Tribal Governments
A-88	Indirect Cost Rates, Audit, and Audit Follow-up at Educational Institutions
A-102	Cooperative Agreements with State Grants and Local Governments
A-110	Uniform Administrative Requirements for Grants and Other Agreements with
	Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations
A-122	Cost Principles for Nonprofit Organizations
A-123	Management Accountability and Control
A-127	Financial Management Systems
A-128	Audits of State and Local Governments
A-129	Policies for Federal Credit Programs and Non-Tax Receivables
A-133	Audits of States, Local Governments and Other Nonprofit Organizations
$G\Delta\Omega$	Government Auditing Standards

INTERNET ACCESSIBLE

To access the 1998-99 Orange Book and various other Office of Inspector General materials on the Internet, use the following address: